STRATEGIC AND PERFORMANCE PLAN

FY 2002 - FY 2004

February 2001

VETERINARY SERVICES MISSION

VS protects and improves the health, quality, and marketability of our nation's animals, animal products, and veterinary biologics by:

- preventing, controlling, and/or eliminating animal diseases, and
- monitoring and promoting animal health and productivity.

VETERINARY SERVICES STRATEGIC PRINCIPLES

COLLECTIVE WORK FORCE

Recognize that VS personnel are only part of a core animal health staff in the U.S. Strengthen the VS organization by reducing internal fragmentation. Build solid partnerships with the other members of the core animal health staff (i.e., state, federal, and international counterparts; private veterinarians; industry personnel; and academia).

COMPREHENSIVE ANIMAL HEALTH APPROACH

Recognize a spectrum of animal health needs from endemic disease situations to epizootic diseases to program diseases to emerging disease situations. VS actions and involvement across this spectrum will vary. Opportunities exist for VS to provide additional support for those diseases which fall on the spectrum between endemic and traditional program diseases.

RIGHT DATA AT THE RIGHT TIME

Develop a comprehensive approach to animal health monitoring and surveillance which can address needs in trade support, regionalization, quality assurance, emerging animal health issue identification, etc.

PUBLIC SERVICE

Utilize VS' animal production expertise and resources (field force, laboratories) to address veterinary public health and environmental issues.

ANIMAL KINGDOM

Recognize that VS has a responsibility to serve <u>all</u> animals because of their potential effects on animal and public health and food safety.

TECHNOLOGY FOR TODAY AND TOMORROW

Maintain worldwide leadership in applying technology to animal health issues.

FLEXIBILITY

Demonstrate greater flexibility in the VS management culture, leadership style, and in the development of new initiatives.

VISIBILITY

Take advantage of specific expertise in the area of public affairs to increase VS visibility.

NEW FUNDING APPROACHES

Broaden VS' funding base by exploring new, nonappropriated sources.

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Introduction

In February 1999, VS[1] issued a Strategic Plan to guide planning and budgeting in VS over a period of years. The intention was to examine the plan annually, make revisions as needed, and establish targets for outyears. This document updates the VS Strategic Plan to cover FY 2002 through FY 2004.

External Factors Affecting VS Strategy

As the 21st century begins, the value of American livestock and poultry industries has reached $100 billion and continues to rise. Global trade in animals and their products, and international travel and migration, are also on the rise. In 2000, almost 17 million farm animals were expected to pass through U.S. inspection points, and 20 million wild animals or exotic pets were also expected to enter from abroad. Over 100 million people were due to travel to the U.S. in 2000, and 1.75 million illegal aliens were expected to enter this country that same year. Increases in trade and travel, coupled with major disease outbreaks affecting key exporters in the global marketplace, challenge VS' ability to prevent disease incursions.

Consolidation and vertical integration have drastically changed animal production over the past two decades. Large corporate farming enterprises employ modern methods of production and distribution, and consolidated packers and processors exercise significant leverage on producers. Similarly, consolidation among retail grocers has grown, and retail giants such as WalMart have increased their market shares and influence on meat sales in the U.S. Small farmers and animal producers often have difficulty competing against the large players who dominate the supply chain for animal products. Some analysts predict that e-commerce will soon revolutionize the connections between agricultural producers, processors, and retailers. How e-commerce will affect trends in industry consolidation remains to be seen.

The VS mandate has changed over the last decade and as a result, the organization’s customer base has become more expansive. Customers served include producers, regulated parties, cooperators, consumers, and others who share an interest in animal health programs and activities. Safeguarding animal health has become an increasingly complex challenge made even more demanding by an ever-changing global economy and international agreements. In addition, heightened

[1] The following acronyms are used frequently throughout this plan: APHIS (Animal and Plant Health Inspection Service), USDA (United States Department of Agriculture), VS (Veterinary Services), NVSL (National Veterinary Services Laboratory), CEAH (Centers for Epidemiology and Animal Health), CVB (Center for Veterinary Biologics), VSMT (Veterinary Services Management Team), AHP (Animal Health Programs), NCIE (National Center for Import/Export), OIE (Office International des Epizooties). Other acronyms used in the plan are defined as they occur.

awareness about emerging diseases, invasive species and potential risks posed by the spillover of wildlife diseases to domestic livestock are exacting pressures on VS. In addition, VS is confronted not only by single agent etiologies but also multifactorial disease syndromes, noninfectious disease agents, and impaired productivity. In addition to biomedical sciences, techniques such as risk analysis and economic modeling are needed for decision making. VS is responding to these new challenges with a smaller staff.

Maturing industries, such as aquaculture and farming of alternative livestock, including bison and cervids, are also demanding new services and nontraditional responses from VS and the organization is having to adjust its work force and its scientific and technical expertise accordingly. Aquaculture production continues to increase dramatically. Populations of alternative livestock, such as deer, elk, and llama, also continue to increase rapidly.

The veterinary biologics and diagnostic industries have also changed significantly. Scientific advances, heightened consumer awareness, and the international harmonization of requirements demands continuous review of program requirements. New methods of production, including biotechnology, have had major impacts on the number, type, and quality of animal treatments. With each new method of production adopted by the industry, the Agency has had to identify hazards and develop appropriate risk management procedures in the form of standard test requirements and regulatory procedures to assure purity, safety, potency, and efficacy of biologics. Rapid diagnostic tools--some based on existing testing methods, and some based on genetics--are also increasingly available to practitioners and the public for quick, presumptive diagnoses of certain disease conditions.

Genetic sequencing projects are underway to better understand the biological makeup of pigs, cows, dogs, cats, and other animals. New information technologies have been developed to process the reams of genetic data, and the field of bioinformatics has been spawned. As more and better genetic data emerge from these and other research efforts, a range of new tools and uses for animals becomes possible. Cloning animals for resistance to specific diseases or retention of positive traits holds promise. Transgenic animals have been used to produce a range of human proteins and pharmaceuticals. Transplantation of animal organs into humans is being researched and developed. While society must still resolve ethical questions surrounding the applications of genetic information, the technology moves ahead.

The public has become increasingly more attentive to health, environmental, and animal welfare issues. The public expects agriculture to perform many tasks, including environmental stewardship and production of safe and inexpensive food. Animal products continue to provide more than 60 percent of the protein consumed in U.S. diets. In carrying out daily activities, VS employees must keep at the forefront issues concerning the use of animals and the impact animal health programs could have on the environment, human health, and public perception.

Public awareness of animal disease issues is fueled by the national media. *Business Week* magazine recently published (September 2000) an article that highlighted possibilities of agroterriorism on one hand, and threats such the African tick, *Amblyomma marmoreum*, a known vector for heartwater, hitchhiking into this country on imported tortoises. The ability of West Nile virus to kill animals, birds, and humans was also described. The author quantified the huge economic effects in other countries of recent outbreaks of foot-and-mouth disease, bovine spongiform encephalopathy (BSE), and viruses such as influenza and Nipah.

To continue to meet the changing needs of animal producers and other members of VS' expanding customer base, VS will need to continually enhance its surveillance, detection, and emergency management systems to prevent, control, or stamp out foreign animal disease incursions and emerging domestic diseases. VS must also be ready to respond to disease incidents caused by agroterrorism. Additionally, VS must effectively and appropriately support international trade, address human health and environmental concerns related to animal health programs, and partner with producers and other stakeholders to implement animal health quality assurance and certification programs which assist producers in marketing their goods in domestic and international markets.

Plan Format

Like the original strategic plan, this document emphasizes program goals and objectives. Several objectives have been added and others have been modified from the February 1999 plan.

The wide array of VS objectives are organized under four major goals. Table 1 provides a complete list of all of VS' key objectives. Figure 1 displays these objectives according to their developmental stage. Objectives which are well established are separated in figure 1 from those, such as Brucellosis, which are changing their focus and those, such as Production Process Auditing/Certification, which are under development. VS' various offices and organizational levels are involved in these goals and objectives to differing degrees.

This plan has three sections.

- The first section contains VS' programmatic goals and objectives. These goals and objectives are linked to the measures, baselines and targets found in Appendix A. More extensive descriptions of each objective are provided in Appendix B.

- The second section outlines VS' special initiatives.

- The third section discusses how this Strategic Plan links with the Civil Rights/Equal Employment Opportunity Strategic Plan and the VS Workforce Plan.

Section I - Goals and Objectives

Mission

VS protects and improves the health, quality, and marketability of our nation's animals, animal products, and veterinary biologics by:
- preventing, controlling, and/or eliminating animal diseases, and
- monitoring and promoting animal health and productivity.

Vision

Together with its customers and stakeholders, VS employs innovative methods to achieve ever higher standards of animal health.

Goals

VS' four goals are aligned with APHIS' goals and with the needs of VS' stakeholders. Achievement of these goals requires broad interaction of all VS program, staff and scientific units.

Goal 1. Safeguard the U.S. from the occurrence of adverse animal health events. *(Adverse animal health events can result from the real or perceived impacts of diseases, pests, vectors, toxins, or natural disasters on productivity, trade, or public health.)*

Goal 2. Monitor the health and productivity of U.S. animal populations and monitor the health-related attributes of animal products and veterinary biologics.

Goal 3. Enhance the health status of U.S. animal populations by anticipating and responding to new or emerging threats and by managing, controlling, or eradicating those already identified.

Goal 4. Expand the domestic and international marketability of U.S. animals, animal products, and veterinary biologics.

Among VS' four goals, Goal 1 Safeguarding is paramount. Completing the eradication programs including, brucellosis, bovine tuberculosis, and pseudorabies (Goal 3 and surveillance under Goal 2),

are also high priorities. Other Goal 3 and Goal 2 activities follow as priorities. Expanding marketability (Goal 4) follows as the fourth most important goal.

Objectives

For each of these goals, VS has identified a number of objectives for the next three years. Table 1 summarizes these goals and objectives in a single matrix. Responding to a foreign animal disease would become VS' top priority were one to occur in the U.S. Other top priority objectives for VS are: **Import Activities** to prevent the introduction of animal diseases, **Cattle Fever Tick** activities to prevent the establishment of cattle fever ticks, **Emergency Management** activities focused on preparing for potential incursions of high risk diseases, **Nonindigenous Invasive Species** activities aimed at preventing the introduction and establishment of foreign species, **Emergency Response** activities focused on addressing adverse animal health events when they do occur in the U.S, **Brucellosis eradication** in cattle, bison, and cervids, **Tuberculosis eradication** in ruminants, **Pseudorabies eradication**, **Scrapie control and eradication**, and **Swine brucellosis eradication**.

Each objective included in the Strategic Plan links to a set of performance measures. Within the plan a brief description is provided for each objective along with the corresponding FY 2004 performance expectation. Detailed annual performance measures and targets for FY 2002, FY 2003, and FY 2004 are listed in Appendix A. More detailed descriptions of each objective are provided in Appendix B.

In addition to working toward the objectives outlined in this plan, the VSMT encourages national, regional, and area offices and specialized units to explore new areas of activity.

Goal 1 - Safeguard the U.S. from the occurrence of adverse animal health events

Safeguarding the U.S. from adverse animal health events has always been a key element of VS' mission. Changing transportation patterns and increasing global trade and travel continue to challenge VS' ability to carry out this safeguarding role. VS is highly dependent upon other APHIS units, International Services and, especially, Plant Protection and Quarantine, to carry out safeguarding activities. In partnering with these units, VS must clearly communicate the levels of risk associated with actual and potential pathways along which foreign animal diseases and pests may be introduced.

1.1. **Import Activities:** Safeguard the United States from adverse animal health events related to the importation of animals, animal products or veterinary biologics.

- ✓ **animals and animal products** - *No foreign animal disease outbreaks will be associated with imported animals or animal products from FY 2002 through FY 2004.*
- ✓ **biologics** - *Throughout FY 2002 to FY 2004, no foreign animal disease introductions will be associated with imported veterinary biologics despite a 12 percent increase (over FY 1999) in the number of doses of veterinary biological products imported.*
- ✓ **laboratory testing** - *NVSL personnel will perform an increasing number of international proficiency panels annually as part of ongoing efforts towards ISO 17025 accreditation, reaching 9 proficiency panels annually by FY 2004.*
- ✓ **global animal health intelligence** - *Global animal health events will be monitored and, 95 percent of the impact assessments prepared for global animal health events will be issued within 5 working days of first notification during FY 2003 and FY 2004.*
- ✓ **risk assessment** - *By FY 2004, 80 percent of completed risk assessments will include all of the WTO-SPS Agreement elements*.

1.2 Cattle Ticks: Prevent the establishment of cattle fever ticks and their associated diseases. Throughout FY 2002 to FY 2004, 100 percent of the cattle fever tick outbreaks occurring outside the quarantine zone will be eliminated in less than 12 months.

1.3 Emergency Management: Prepare for potential incursions of high risk diseases. During FY 2002 to FY 2004, APHIS will develop a disease specific response plan for the most important or high risk foreign animal diseases and 6 cross-cutting response plans covering topics such as disposal, euthanasia, and compensation. An emergency management educational curriculum will be developed during FY 2001. By FY 2004, 85 percent of Area Veterinarians (or designees) and 65 percent of State Veterinarians (or designees) will have completed this educational curriculum.

1.4 Nonindigenous Invasive Species: Prevent the introduction and establishment of foreign species capable of harming domestic livestock, poultry, wildlife, and aquacultural products. This includes foreign species that may cause ecological and financial damage by serving as vectors of disease agents or destroying fisheries. Pathways of introduction of vectors or vector-borne disease agents will be

identified by FY 2002 and regulations to prevent introductions will be developed and implemented by FY 2003.

Goal 2 - Monitor the health and productivity of U.S. animal populations and monitor the health-related attributes of animal products and biologics

Information regarding the health status, productivity and health-related attributes of U.S. animal populations, animal products, and biologics is at a premium. Consumers are demanding increased information about the products they purchase. International agreements require scientific data to verify disease status claims. Development of national animal identification systems, common standards for a national reporting system, and an ability to detect emerging animal health issues are required to maintain public confidence and international trade. Funding limitations demand that VS ensure that each of its surveillance and monitoring programs provide maximum value in meeting these increasing information demands.

2.1. **Emergency Management System:** Rapidly detect the presence of foreign animal diseases, pests or other threats to U.S. animal populations or animal products including those related to bioterrorism. By FY 2004, 100 percent of States and Territories will have met the surveillance standard as set in the document entitled, "Standards for State Animal Health Emergency Management Systems - DRAFT - August 1999". Also by FY 2004, 650 foreign animal disease investigations will be carried out annually.

2.2. **Biologics:** Perform post-marketing monitoring of veterinary biological products to more accurately reflect the safety and efficacy of veterinary biologics used in the field. In FY 2003, there will be 1 adverse event reported for each 855,555 doses released. Also in FY 2003, a new mandatory adverse events reporting system will be instituted. The mandatory system is expected to increase the number of adverse events reported.

2.3. **Diagnostics:** Provide laboratory diagnostic services, products, and training to support animal disease surveillance. During FY 2002 to FY 2004, at least 1 of the disease surveillance surveys conducted each year (such as bluetongue and Salmonella serotyping) will show an increase in quality as measured by increased accuracy, decreased turnaround time, or decreased cost.

2.4. **Surveillance:** Carry out a range of surveillance methods which provide information related to control and eradication programs and to the prevalence of specific diseases in U.S. animal populations.

- ✓ **BSE** - *By FY 2004, 5,000 adult/downer animal brains will be examined annually, more than five times the number examined in FY 1998 and well above OIE surveillance goals. Also by FY 2004, surveillance within the U.S. will exceed OIE surveillance goals on a regional basis.*
- ✓ **bovine tuberculosis** - *Surveillance will be increased to reach the level needed to detect bovine tuberculosis in any population of livestock. By FY 2003, a total of 10,000 animals with lesions will be sampled on farm and at slaughter annually and this level will be maintained in FY 2004.*
- ✓ **brucellosis** - *Enhanced surveillance will be critical for a minimum of 5 years after the U.S. is declared free of brucellosis. Continued surveillance after the 5 year period may be required to address concerns arising from swine and wildlife. Throughout FY 2002 to FY 2004, 11 million cattle and bison will be sampled annually and 95 percent of slaughter animals will be sampled.*
- ✓ **chronic wasting disease** - *By FY 2002, all states with potential presence of chronic wasting disease will be participating in national surveillance and, by FY 2004, 15,000 farmed cervids will be sampled annually.*
- ✓ **classical swine fever** - *In FY 2001, a revised sampling plan will be developed for classical swine fever. The new plan will be implemented in FY 2002. The plan will ensure coverage of high risk areas.*
- ✓ **EIA** - *By FY 2004, 2 million animals will be sampled annually.*
- ✓ **Johne's** - *A surveillance system for Johne's will be developed and implemented. By FY 2004, sampling will have risen to 600 herds annually.*
- ✓ **pseudorabies** - *Throughout FY 2002 to FY 2004, 20 percent of sows and boars will be sampled at slaughter annually.*
- ✓ **scrapie** - *During FY 2002 through FY 2004, sampling will increase to 100,000 sheep annually.*
- ✓ **swine health protection** - *Increase the level of understanding of the food waste industry of the need to prevent the introduction and dissemination of foreign animal diseases; enhance surveillance nationwide to ensure full compliance with applicable federal and state laws. Throughout FY 2002 to FY 2004, 98 percent of inspected premises will remain in compliance.*

2.5. National Animal Identification System: In partnership with industry and State governments, develop a reliable and cost-effective system of animal identification for use in the United States. The system will be developed by FY 2001 and fully implemented by FY

2003. By FY 2004, 95 percent of the traces involving cattle, swine, and captive cervids, will be successful as will 80 percent of the traces involving sheep, goats and equine.

2.6. Emerging Animal Health Issue Detection: Rapidly detect the presence of an emerging animal health issue. Establish a central process for gathering, reviewing, and evaluating data on emerging animal health issues. An Emerging Animal Health Issues Tracking System will be created by FY 2001 and the percentage of individuals reporting issues will increase by 10 percent annually throughout FY 2002 to FY 2004.

2.7. **Monitoring and Surveillance Initiative:** Develop a comprehensive and coordinated approach to animal health monitoring and surveillance. This approach will provide information needed for emerging disease issues, trade risk assessment, regionalization, and control and certification programs. VS will implement a model surveillance system for swine diseases by FY 2003 and extend the system to other species during FY 2004.

2.8. **National Animal Health Monitoring System:** Determine the health and productivity of U.S. animal populations. In FY 2001, utilizing the recommendations from the 2000 NAHMS Program Review, a determination will be made as to whether to continue the current survey rotation and/or whether the time between reviews should be lengthened, or whether a different system is needed to assign resources effectively to the US' various animal industries, and to serve the needs of VS programs and monitoring and surveillance activities. Throughout FY 2002 to FY 2004, at least 80 percent of customers surveyed will indicate a high level of confidence in NAHMS credibility and that they are satisfied/highly satisfied with the service and products NAHMS provides.

Goal 3 - Enhance the health status of U.S. animal populations by anticipating and responding to new or emerging threats and by managing, controlling, or eradicating those already identified

After many years of work, several major disease programs will move from an eradication phase into an intensive monitoring and surveillance phase to win international recognition of U.S. disease-free status. At the same time, other disease programs will be modified as the focus shifts from domestic stock to potential disease reservoirs in wildlife populations.

VS emergency "response" on both a national and an area level will be honed through disease outbreak test exercises and by participation in disaster response efforts. Both will offer opportunities to evaluate response strategies, infrastructure, communications, and partnerships. VS and its partners will work together on a more systematic approach to emerging animal health events to prevent a recurrence of the lack of early action which is thought to have lead to the dispersion of PRRS throughout the swine population.

3.1. **Emergency Management System:** Respond effectively to adverse animal health events and identify agencies and organizations which can assist affected industries and producers in recovering from their effects. All States and Territories will meet the state standards for emergency management by FY 2004.

3.2. **Brucellosis:** Build on the eradication of brucellosis from U.S. domestic cattle and captive bison and cervids with the eradication of brucellosis from domestic swine by 2004; work to eliminate brucellosis from bison and elk in the Greater Yellowstone Area; prevent the transmission of brucellosis from other species to domestic livestock, and make progress toward the eradication of brucellosis in other species (goats, feral swine, caribou/reindeer).

- ✓ **cattle/bison** - *By FY 2003, 50 States and 3 Territories will be class free and no herds will be newly infected. This level will be maintained in FY 2004. Cattle brucellosis activities will transition to surveillance and VS will treat brucellosis in cattle as an emergency.*
- ✓ **captive cervids** - *During FY 2002 to FY 2004, no herds will be newly infected.*
- ✓ **swine** - *By FY 2004, 50 States and 3 Territories will be class free.*

3.3. Tuberculosis: Eradicate tuberculosis from cattle, bison, goats, and captive cervids and prevent the transmission of tuberculosis from other livestock and wildlife. By FY 2004, 49 States/Territories will be accredited-free.

3.4. **Pseudorabies:** Eradicate pseudorabies from the U.S. domestic swine population, prevent the transmission of pseudorabies from feral swine to domestic swine, and make progress toward the eradication of pseudorabies in feral swine. By FY 2004, 50 States and 2 Territories will be in Stage V and there will be no newly infected herds.

3.5. Scrapie: Control and ultimately eradicate scrapie from the U.S. By FY 2004, 95 percent of Infected or Source flocks will be on flock plans or removed from Infected or Source flock status.

3.6. **Poultry Initiatives:** Respond effectively to poultry industry requests to enhance poultry health in the United States. (see also 4.4 Production Process Auditing and Certification)

- ✓ **avian influenza** - *At the industry's request, develop a program to reduce the incidence of low pathogenic avian influenza infections in the live bird marketing system. Throughout FY 2002 to FY 2004, no live bird retail markets will be positive for low pathogenic avian influenza.*
- ✓ **National Poultry Improvement Program** - *Reduce cases of Mycoplasma gallisepticum in turkey breeding flocks by 10 percent in FY 2002 and 5 percent in each of FY 2003 and FY 2004. Increase the participation of meat-type chicken breeding flocks to 45 percent for the Salmonella enteritidis clean program and 25 percent for the new avian influenza clean classification by FY 2004. Have no more than 3 cases of Salmonella pullorum each year throughout FY 2002 to FY 2004.*

3.7. Johne's: Control and ultimately eradicate Johne's from the United States. By 2004, 4,000 herds will be participating in a certification program and 600 herds will be advancing in the program.

3.8. **Equine Programs:** Work with the equine industry to enhance equine health in the U.S.

- ✓ **EIA** - *Work with state officials to expand disease status from control to eradication. Increase the percentage of positive horses under state approved management plans to 100 percent by FY 2004.*
- ✓ **Slaughter horse transport regulations/enforcement** - *Improve transport conditions so that, by FY 2002, 100 percent of targeted horses (based on random samples in designated states) are transported humanely; maintain these conditions through FY 2004.*
- ✓ **BLM wildhorse and burro program consultation** - *By FY 2004, 100 percent of the BLM herd consultation management areas will involve VS staff in herd projects.*

3.9. Chronic wasting disease - Eliminate CWD from farmed elk operations in the United States. By FY 2004, 75 percent of farmed elk herds will be participating in a national certification program.

3.10. Wildlife Initiatives: Address disease issues in wildlife populations to protect the health status of domestic livestock. By FY 2004, actions will be taken for five VS program diseases (brucellosis, bovine tuberculosis, chronic wasting disease, pseudorabies, and Johne's)

3.11. **Biologics:** Protect animal health by ensuring the purity, safety, potency, and efficacy of veterinary biological products available to the marketplace. In FY 2004, 3.8 percent of veterinary biological serials will be withheld from the market because they do not meet the standards set forth during licensure for purity, potency, safety, and efficacy.

3.12. **Diagnostics:** Improve laboratory support to disease investigation efforts and control/eradication programs. During FY 2002 through FY 2004, 3 peer-reviewed testing programs will show improvement.

Goal 4 - Expand the domestic and international marketability of U.S. animals, animal products, and biologics

The rapid development of e-commerce is a challenge to VS' ability to assist U.S. animal industries in marketing efforts. VS will need to align its efforts in international negotiations and harmonization with up-to-date ways of doing business in an age in which business is conducted electronically. "E-government" requirements will have to be met. VS will also need to assure trading partners that accredited veterinarians can effectively carry out their responsibilities.

4.1. **Export Program.** Further the export of U.S. animals, animal products, and veterinary biologics and promote timely and efficient health certification processes for U.S. exports. Partner with the private sector to develop a process for proactively identifying markets for U.S. animal industries. Between FY 2002 and 2004, 4 new or modified export protocols will facilitate U.S. access to new markets. Fifty-five export markets will receive aquaculture products by FY 2004. All export certificates for animals will be issued electronically by FY 2004.

4.2. Veterinary Accreditation. Ensure that accredited veterinarians have the tools needed to further advance disease prevention and emergency preparedness in the U.S. Program changes recommended during a review conducted in FY 1998/FY 1999 are being used to develop program modifications which will be implemented by FY 2004/2005 through rulemaking.

4.3. **Disease Status Certification:** Provide disease-status certification programs to verify freedom of livestock, poultry, fish, and marine species from diseases of domestic and international trade and marketing concern.

- ✓ **aquaculture -** *Between FY 2002 and FY 2004, 5 new States will establish voluntary programs where APHIS endorses aquatic animal health certificates for international exportation.*
- ✓ **sheep** - *Certify 325 flocks free of scrapie by FY 2004. By FY 2004, 1,140 flocks will be participating in the Scrapie Voluntary Certification Program.*

4.4. Production Process Auditing and Certification[2]: Provide production process auditing and certification at the farm level to improve the quality and safety of animal-derived food products. APHIS will partner with FSIS to link on-farm and in-plant HACCP efforts to improve both quality and safety attributes.

- ✓ **trichinae** - *Implement a national on-farm trichinae certification program. By FY 2003, the certification program will be running in all 50 states and continued in FY 2004.*
- ✓ **auditing service delivery -** *Develop and market the service of standardizing and auditing production systems and export facilities. By FY 2004, auditing pilots will be running in eight VS field offices.*
- ✓ **egg quality assurance** - *Audit United Egg Producers quality assurance activities to reduce the incidence of Salmonella enteritidis in table eggs. The number of farms audited during FY 2002 through FY 2004 will be determined based on the participants in the voluntary program.*
- ✓ **toxoplasma** - *Implement a national on-farm toxoplasma certification program. During FY 2002 through FY 2004, certification pilots will be implemented in 2 major slaughter plants involving producers from 3 key states.*

4.5. Diagnostics. Approve laboratories to test animals for interstate/international movement and/or participation in certification programs. The number of approved laboratories/tests will increase by 5 percent each year from FY 2002 to FY 2004.

4.6. Biologics. Actively participate in the international harmonization of regulatory standards for veterinary biologic products. Publish four harmonized regulations, standards, guidelines or agreements by FY 2004.

[2] "Certification" here refers to a process whereby a herd is conferred a status based upon the implementation of a series of cooperatively developed standards that, when implemented, produce a product of known quality. Herds obtaining certification will have implemented the same set of standards and been uniformly evaluated. "Auditing" refers to a process that transmits information within a buyer-supplier relationship. The buyer defines production specifications for suppliers, suppliers declare to have met those specifications in their production system, and a third party audits the suppliers to ensure that specifications have been met. Auditing standards are set through buyer and supplier negotiations and must have characteristics that can be independently verified; unlike certification, no uniform national standards need be established.

Section II - VS Special Initiatives

Animal Health Safeguarding Review: In Fall 2000, VS contracted with the National Association of State Departments of Agriculture (NASDA) to conduct a review of its safeguarding activities. Key safeguarding components to be assessed are: collection, analysis, and use of international information; exclusion; domestic detection and surveillance; and response. Safeguarding animal health has become an increasingly complex challenge made even more demanding by an ever-changing global economy and international agreements. Recommendations from the NASDA review are expected by June 2001.

Science and Technology Infrastructure: Complete the planned infrastructure improvements at NVSL (both in Ames and at Plum Island) and CVB. NVSL/CVB facilities in Ames were constructed in the late 1970s. Today, the facilities have reached the end of their design and structural lifespan. ISO 17025 standards require more up-to-date facilities. While investments have been made for repair and maintenance, virtually every critical system - ventilation, electrical, sewage treatment, biocontainment, incineration, and heating and cooling - is antiquated. USDA has requested funding for a new facility in Ames to meet urgent national needs for research, diagnosis, and product testing related to animal health. The proposed facility will replace facilities currently used by NVSL, CVB, and the Agricultural Research Services' National Animal Disease Center.

Government Paperwork Elimination Act (GPEA): GPEA requires Federal agencies, by October 21, 2003, to allow individuals or entities that deal with the agency the option to submit information or transact with the agency electronically, when practicable, and to maintain records electronically, when practicable. GPEA is considered to be an important tool for improving customer service and governmental efficiency through the use of information technology. VS has identified fourteen primary forms it intends to automate per GPEA requirements. A timeline for completion will be established during FY 2001. In addition to automating the forms, VS will take steps to modify the business processes involving the targeted forms so that additional operational benefits can be achieved.

Marketing and External Communications: VS has strong working relationships with some of its constituents, and some constituents are even motivated to speak on the organization's behalf. However, VS has been modest in publishing and sharing the results of its successes and therefore needs to establish a value for the organization and its services in the minds of all constituents, the public, and Congress. VS

published a *Marketing and External Communications Plan* in October 2000. Carrying out this plan will proactively promote the organization and its programs. The action plan includes increasing industry and general media contacts through introductory calls, letters, and packets; exhibiting at selected conferences and meetings; and visiting with state officials, producer groups, and veterinary schools.

Section III - Integration of Strategic Plan and Civil Rights/EEO and Workforce Planning Efforts

Since 1993, the full-time equivalent staff-years accumulated by VS employees have declined from 1,746 to 1,381 in 2000. In July 2000, VS published its *Work Force Plan* for Fiscal Years 2000 - 2004. The plan projected changes in the animal agriculture environment and internal work environment, and it identified potential problems and future opportunities. The *Work Force Plan* is a key strategy to help VS achieve its strategic goals considering that it must acquire, develop, and maintain a quality work force to meet current and future needs. The plan identified gaps in the work force and work place, thus providing information that will assist managers in dealing effectively with the organization's future human resource needs.

Although the work force is 45 percent female and 20 percent minorities, there is still under representation in many employment categories when comparisons are made with civilian labor force statistics. VS prepared a Civil Rights (CR) Strategic Plan in 1999 (covering 1999 - 2001) to address under representation and other CR issues.

Key objectives identified for VS in the VS Civil Rights Strategic Plan are listed below. The newly formed National Civil Rights Leadership Committee (NCRLC) will monitor VS progress on these objectives.

- ✓ Manage its work force through sound human resource management practices (*e.g., hiring, promotions, career development, awards recognition, performance management, employee utilization, and conflict management*).
- ✓ Reach out to under-represented and under-served customers who may require our services, or to institutions that serve under-represented groups or under-served communities that may be able to assist VS with program delivery. A major outreach initiative planned over the next several years is to train students who are enrolled in Land Grant Colleges and

Universities (1862 and 1890) to assist the organization in vaccinating animals in the event of an emergency. This effort is being spearheaded by the NCRLC. Another outreach initiative planned is to recognize areas of the country owned and populated by Native Americans, as appropriate, as free of program diseases that required extensive eradication efforts (e.g., brucellosis and tuberculosis).

- ✓ Comply with the Department's environmental justice* goals in carrying out its programs.
- ✓ Involve small, disadvantaged, or other preference category businesses, in delivering program services.

Examples of how the Civil Rights strategic objectives can be better tied to VS programmatic objectives include:

- ❖ Form more partnerships with colleges and universities that have large enrollments of minorities and women, and increase funding for grants and cooperative agreements with these institutions accordingly.

- ❖ Properly dispose of pesticides or acarcides used in the Cattle Tick Program (or other animal health programs requiring their use) to ensure that they do not cause harm to the environment or to any member of society.

- ❖ Provide opportunities for minority and low-income populations to participate in planning, analysis, rulemaking, and decisions that affect their health, environment, or economic status, including identification of program needs and program design.

- ❖ Identify, prevent, and/or mitigate, to the greatest extent practical, adverse human health or environmental effects of an emergency response to an animal disease threat on minority and low-income populations.

- ❖ Where feasible, procure goods and services from minority and women-owned businesses to support program needs.

** Note: Environmental justice is identifying and addressing adverse human health and environmental effects of programs, policies, and activities on minority populations and low-income populations.*

Table 1. Matrix of Four Major VS Goals with Program Objectives or Initiatives

Goals	1. Safeguard the U.S. from the occurrence of adverse animal health events	2. Monitor the health and productivity of U.S. animal populations and monitor the health-related attributes of animal products and veterinary biologics	3. Enhance the health status of U.S. animal populations by anticipating and responding to new or emerging threats and managing, controlling, or eradicating those already identified	4. Expand the domestic and international marketability of U.S. animals, animal products, and veterinary biologics
Objectives	*1.1 Import Activities ✓ animals/animal products ✓ biologics ✓ laboratory testing ✓ global animal health intelligence ✓ risk assessment	2.1 Emergency Management System	*3.1 Emergency Management System	4.1 Export Program
		2.2 Biologics	*3.2 Brucellosis ✓ cattle/bison ✓ captive cervids ✓ swine	4.2 Veterinary Accreditation
		2.3 Diagnostics		4.3 Disease Status Certification ✓ aquaculture ✓ sheep
		2.4 Surveillance ✓ BSE ✓ bovine tuberculosis ✓ brucellosis ✓ chronic wasting disease ✓ classical swine fever ✓ EIA ✓ Johne's ✓ pseudorabies ✓ scrapie ✓ swine health protection	*3.3 Tuberculosis	
	*1.2 Cattle Ticks		*3.4 Pseudorabies	4.4 Production Process Auditing and Certification ✓ trichinae ✓ auditing service delivery ✓ egg quality assurance ✓ toxoplasma
	*1.3 Emergency Management System		*3.5 Scrapie	
	*1.4 Nonindigenous Invasive Species		3.6 Poultry Initiatives ✓ avian influenza ✓ NPIP	
			3.7 Johnes	
		2.5 National Animal Identification Systems	3.8 Equine Programs ✓ EIA ✓ Slaughter horse transport ✓ BLM wildhorse/burro program	4.5 Diagnostics
		2.6 Emerging Animal Health Issue Detection		4.6 Biologics
		2.7 Monitoring and Surveillance Initiative	3.9 Chronic Wasting Disease	
		2.8 National Animal Health Monitoring System	3.10 Wildlife Initiatives	
			3.11 Biologics	
			3.12 Diagnostics	
	Science and technology infrastructure improvements			

** Top VS priority.*

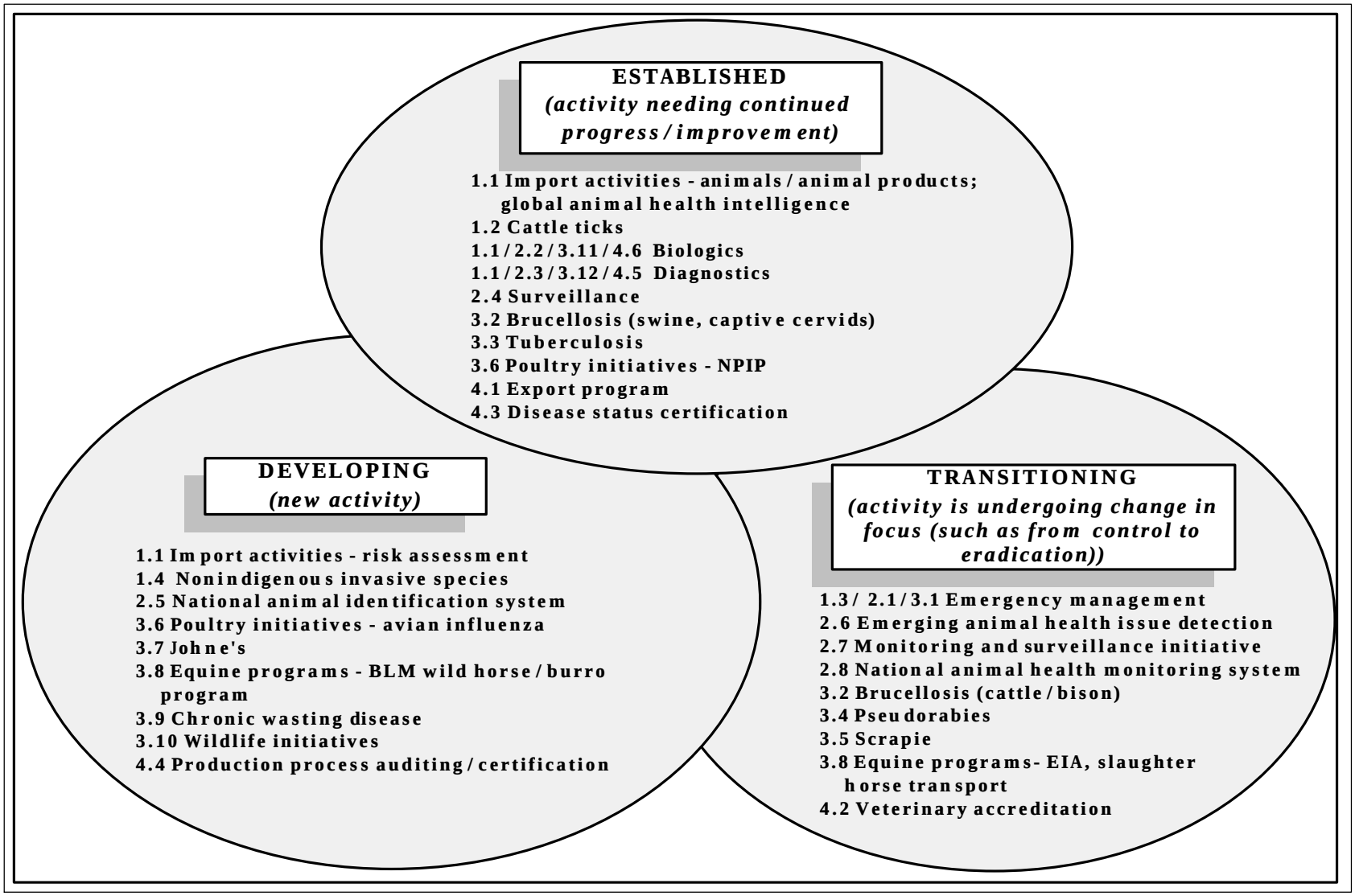

Figure 1: Developmental Stage for Each VS Objective

Appendix A: Performance Measures and Targets for Each Goal/Objective

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
Goal 1. Safeguarding					
▪ **1.1 Import activities** ✓ animals and animal products	Number of foreign animal disease outbreaks associated with the importation of animals and animal products	0	0	0	0
✓ biologics	Doses of product imported without an introduction of disease	101,268,917	7% increase over FY 1999	10% increase over FY 1999	12% increase over FY 1999
✓ laboratory testing	Number of international proficiency panels performed by NVSL personnel	1	7	8	9
✓ global animal health intelligence	Percentage of impact assessments of key global animal health events issued within 5 working days of first notification	n/a	90%	95%	95%
✓ risk assessment	Percentage of risk assessments that include all of the WTO-SPS Agreement elements	approx 30%	60%	70%	80%
▪ **1.2 Cattle ticks**	***Percentage of cattle fever tick outbreaks outside the quarantine zone which are eliminated in less than 12 months. (*Measure is included in APHIS Performance Plan)**	100%	100%	100%	100%
▪ **1.3 Emergency Management System**	Percentage of disease specific response plan for most important or high risk foreign animal diseases produced	Prioritize set of disease agents for which response plans are needed	75% of the response plan completed	100% of response plan completed	Develop a review cycle for completed plans
	Number of cross-cutting response plans produced annually (includes plans for disposal, euthanasia, compensation)	Develop list of cross-cutting plans needed	2	2	2
	Percentage of Area Veterinarians (or designees) completing emergency management curriculum	n/a	10% (curriculum developed in FY 2001)	50%	85%
	Percentage of State Veterinarians (or designees) completing emergency management curriculum	n/a	10% (curriculum developed in FY 2001)	35%	65%

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
▪ **1.4 Nonindigenous invasive species**	Establish procedures to identify pathways of introduction of foreign vectors and vector-borne diseases into the United States and develop methods to prevent their introduction and establishment.	n/a	Design survey procedures to identify potential pathways of introduction. Conduct risk analysis to determine appropriate actions to prevent introduction.	Publish proposed rules as appropriate based on pathways analysis	Implement regulations
Goal 2. Monitoring					
▪ **2.1 Emergency Management System**	Percentage of States or Territories meeting surveillance standard in "Standards for State Animal Health Emergency Management Systems - August 1999". These surveillance standards include: 1) having a list of reportable diseases, 2) developing an adequate surveillance program, and 3) identifying risks to animal health within the state and conducting targeted surveillance in high risk populations.	n/a	40%	80%	100%
	Number of foreign animal disease investigations	336	510	575	650
▪ **2.2 Biologics**	Ratio of adverse events reported to CVB to the number of doses released to the marketplace	1 per 3 million doses	1 per 4.4 million doses	1 per 855,555 doses; implement mandatory reporting system	New targets to be forecasted as new reporting system is implemented and new baseline is determined
▪ **2.3 Diagnostics**	Number of surveys conducted annually in which quality (as measured by increased accuracy, decreased turnaround time, or decreased cost) is increased	1	1	1	1

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
▪ **2.4 Surveillance**					
✓ BSE	Number of brains submitted nationally from cattle 20 months or older with CNS signs or downers of the same age criteria	979	3,000	4,000	5,000
	Number of brains submitted regionally from cattle 20 months or older with CNS signs or downers of the same age criteria				
	Northwest	n/a	367	489	611
	Southwest	n/a	303	404	505
	Central	n/a	497	664	830
	South Central	n/a	477	636	795
	North Central	n/a	394	525	656
	Northeast	n/a	300	400	500
	Eastern	n/a	203	270	338
	Southeast	n/a	419	558	698
	Other*	n/a	40	54	67
	* (PR, AK, HI)				
✓ bovine tuberculosis	Number of animals with lesions sampled	781	1,000	10,000	10,000
✓ brucellosis	Number of cattle and bison sampled	11 million	11 million	11 million	11 million
	Percentage of animals sampled at slaughter	95%	95%	95%	95%
✓ chronic wasting disease	Number of farmed cervids sampled	577	8,000	10,000	15,000
	***Percentage of states with potential presence of chronic wasting disease participating in national surveillance *(Measure is included in APHIS Performance Plan)**	n/a	100%	100%	100%
✓ classical swine fever	Pending - new performance measures will be developed as new surveillance plan is developed during FY 2001	Pending	Pending	Pending	Pending
✓ EIA	Number of animals sampled	1,600,000	1,800,000	1,900,000	2,000,000
✓ Johne's	Number of herds sampled	0	0	300	600
✓ pseudorabies	Percentage of sows and boars sampled	10%	20%	20%	20%
✓ scrapie	Number of sheep sampled	25	12,000	50,000	100,000

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
✓ swine health protection	Percentage of inspected premises in compliance	95%	98%	98%	98%
▪ **2.5 National Animal Identification System**	Percentage of traces successfully made to the appropriate premises (based on the reason for the trace, i.e., illegal residues, brucellosis, tuberculosis, pseudorabies, etc.)				
	Cattle	n/a	85%	95%	95%
	Swine	n/a	60%	80%	95%
	Sheep and goats	n/a	50%	75%	80%
	Equine	n/a	50%	75%	80%
	Captive cervids	n/a	90%	95%	95%
▪ **2.6 Emerging Animal Health Issue Detection**	Percentage annual increase in individuals reporting issues to the Emerging Animal Health Issues Tracking System	n/a	10% increase (Tracking system will be implemented in FY 2001)	10% increase	10% increase
▪ **2.7 Monitoring and Surveillance Initiative**	Develop and implement integrated systems	n/a	Review results of integrated swine animal health issue surveillance system *(Integrated system for swine developed in FY 2001*)	Continue developing and implementing integrated surveillance models for swine	Evaluate developed systems; use results to further refine systems being developed for additional species
▪ **2.8 National Animal Health Monitoring System**	Percentage of customers surveyed who indicate a high level of confidence in NAHMS credibility and that they are satisfied/highly satisfied with the services and products NAHMS provides	n/a (survey tool being developed)	80%	80%	80%
Goal 3. Responding					
▪ **3.1 Emergency Management System**	***Percentage of States and Territories meeting "standard" for state emergency management system (*Measure is included in APHIS Performance Plan)**	n/a	40	80	100

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
▪ **3.2 Brucellosis**					
✓ cattle/bison	***Number of Class Free States and Territories (*Measure is included in APHIS Performance Plan)**	47	51	53	53
	Number of newly infected herds	35	15	0	0
✓ captive cervids	Number of newly infected herds	0	0	0	0
✓ swine	Number of Class Free States and Territories	49	51	51	53
	Number of newly infected herds	18	5	2	0
▪ **3.3 Tuberculosis**	***Number of States and Territories in accredited free status (including the District of Columbia and Puerto Rico) (*Measure is included in APHIS Performance Plan)**	47	48 plus 1 split status state	48 plus 1 split status state	49
▪ **3.4 Pseudorabies**	***Number of Stage V states (including the District of Columbia) (*Measure is included in APHIS Performance Plan)**	33	49	49	52
	Number of newly infected herds	711	100	0	0
▪ **3.5 Scrapie**	Percent of Infected or Source flocks on flock plans or removed from Infected or Source flock status list during the fiscal year	29%	85%	90%	95%
▪ **3.6 Poultry Initiatives**					
✓ avian influenza	Percentage of live bird retail markets positive for low pathogenic avian influenza	40% (FY 2000)	0	0	0

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
✓ NPIP	Percent reduction in Mycoplasma gallisepticum cases in turkey breeding flocks	6 cases	10% reduction	5% reduction	5% reduction
	Percent of meat-type chicken breeding flocks in the Salmonella enteritidis clean program	15%	35%	40%	45%
	Percent of meat-type chicken breeding flocks in the new avian influenza clean classification	n/a (new program)	10%	15%	25%
	Number of cases of Salmonella pullorum	<3	3 or fewer	3 or fewer	3 or fewer
▪ **3.7 Johne's**	Number of herds in certification program	525	2,000	3,000	4,000
	Number of herds advancing in the certification program	139	450	550	600
▪ **3.8 Equine Programs** ✓ EIA	Percentage of positive horses under state management plan	80%	90%	95%	100%
✓ Slaughter horse transport	Percentage of horses transported humanely *(based on random samples in designated states)*	75%	100%	100%	100%
✓ BLM wildhorse and burro program consultation	Percentage of BLM herd consultation management areas that involve VS staff in herd projects	10%	50%	80%	100%
▪ **3.9 Chronic Wasting Disease**	Percentage of farmed elk herds participating in national certification program	0	30%	50%	75%
▪ **3.10 Wildlife Initiatives**	Number of VS program diseases in which actions are taken to prevent disease transmission to livestock (cummulative)	2	4	5	5 (brucellosis, bovine TB, CWD, pseudorabies, Johne's)

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
▪ **3.11 Biologics**	***Biologics Quality Index = Percentage of veterinary biological serials withheld from the market because they were determined by required testing and manufacturing guidelines to be worthless, contaminated, dangerous, or harmful (*Measure is included in APHIS Performance Plan)**	2.9%	3.6%	3.7%	3.8%
▪ **3.12 Diagnostics**	***Comparison of scores from sequential peer reviews. (*Measure is included in APHIS Performance Plan)**	n/a	1 repeat review; 2 repeat reviews (FY 2001 - FY 2002) show improvement	1 repeat review; 3 repeat reviews (FY 2001 - FY 2003) show improvement	1 repeat review; 4 repeat reviews (FY 2001 - FY 2004) show improvement
Goal 4. Marketing					
▪ **4.1 Export Program**	Number of animals certified for export				
	Aquaculture	40 million	45 million	48 million	50 million
	Livestock	1.04 million	1.1 million	1.2 million	1.3 million
	Poultry	173 million	175 million	180 million	185 million
	Germplasm	10.2 million	10.6 million	10.8 million	11.2 million
	***Number of new or modifed cumulative export protocols facilitating U.S. access to new overseas markets (*Measure is included in APHIS Performance Plan)**	32	46	48	50
	***Number of export markets receiving aquaculture products (*Measure is included in APHIS Performance Plan)**	50	52	53	55
	Number of certificates endorsed for exporting aquacultural products (eggs/fish)	628	900	925	950
	Percentage of export certificates for animals issued electronically	0	20%	100%	100%
▪ **4.2 Veterinary Accreditation**	Implement recommended changes to accreditation program through rulemaking	n/a	Publish proposed rule	Publish final rule	Implement final rule

Goal/Objective	Measurement(s)	FY 1999 Baseline	FY 2002 Target	FY 2003 Target	FY 2004 Target
▪ **4.3 Disease Status Certification**					
✓ aquaculture	Number of states with voluntary certification programs established	6	12	15	17
	Number of farms approved	1	16	24	26
	Number of laboratories approved	6	12	15	17
✓ sheep	***Number of flocks certified free of scrapie (*Measure is included in APHIS Performance Plan)**	32	85	170	325
	Number of flocks participating in the Scrapie Voluntary Certification Program	459	790	950	1,140
▪ **4.4 Production Process Auditing and Certification**					
✓ Trichinae	Number of states participating in certification program	n/a	8 states	50 states	50 states
✓ Auditing service delivery	Number of auditing pilots	n/a	0	4	8
✓ Egg quality assurance	Number of farms audited	As of FY 2000, no participants in voluntary program	TBD based on participants in voluntary program (FDA rules proposed and finalized in FY 2001)	TBD based on participants in voluntary program	TBD based on participants in voluntary program
✓ Toxoplasma	Number of pilots	n/a	0	2 major slaughter plants, producers from 3 key states	2 major slaughter plants, producers from 3 key states
▪ **4.5 Diagnostics**	Number of laboratories/tests approved to conduct animal movement and certification tests	742	5% increase over previous year	5% increase over previous year	5% increase over previous year
▪ **4.6 Biologics**	Harmonization of regulations and standards published and agreements reached	0	1	1	2

Appendix B: Extended Descriptions of Each Objective

Goal 1 - Safeguard the U.S. from the occurrence of adverse animal health events

1.1 Import Activities

✓ **Animals and animal products -**

The National Center for Import and Export (NCIE) issued approximately 9,000 Veterinary Permits for the import of live animals and animal products. Each permit addresses the specific restrictions by which the animal or product can be imported. For animals, these restrictions include conditions of quarantine and testing. For animal products, these restrictions include conditions of processing, certification and distribution, which are evaluated on a case by case basis depending on the particular importation. The purpose of these steps is to assure that, based on the country of origin of the animal or animal product, that the importation will not jeopardize the animal health status of the United States.

When an outbreak of a foreign animal disease occurs in a foreign country, such as occurred in FY 2000 in the United Kingdom with Classical Swine Fever and in South Africa, South Korea, and Japan with Foot and Mouth Disease, NCIE immediately takes steps to prevent the import of those diseases by informing PPQ at all ports of entry and also by canceling numerous permits from the affected countries.

Conversion to electronic format of import application forms by 2002 should reduce incoming calls and increase permit turnaround time leading to improved customer service.

✓ **Biologics**

Interaction with Canadian regulatory officials is continuing under the Canada-United States Trade Agreement (CUSTA) and the North American Free Trade Agreement (NAFTA). The Center for Veterinary Biologics (CVB) is currently at the end of a facilities inspections confidence building step. The confidence building exercise will allow the Canadian Food Inspection Agency (CFIA) and CVB to accept each others on-site facilities inspection in association with the licensing and maintenance of veterinary biological products. A Memorandum of Understanding between CVB and CFIA is currently under review. The next areas for harmonization currently underway affect the licensing and serial release activities for veterinary biological products.

Along with harmonization efforts described in objective 4.6, these activities could drastically increase the number of doses imported (as well as exported) over the next decade. Currently, requests for importation of product for sale and distribution are reviewed and risk assessments are conducted before issuance of an import permit by CVB. This procedure parallels the requirements for licensure of a veterinary biological product. CVB also continues to conduct risk assessments in accordance with international standards for veterinary biologics to assure

appropriate safeguards and mitigations are in place to maintain the position of no foreign animal disease introductions due to veterinary biological products.

✓ Laboratory testing

Safeguarding the United States from the incursion of unwanted animal diseases generally requires the development and maintenance of high quality diagnostic laboratory testing. These types of tests are used to test animals brought into quarantine upon entry into the U.S. One of the ways to increase and maintain our credibility with our international trading partners is to assess our testing capabilities by performing international proficiency exams. In addition, NVSL will have more complete assurance that we can detect the presence of diseases we are concerned about in animals coming into this country. NVSL is striving towards ISO 17025 accreditation. A crucial aspect of attaining ISO accreditation is participation in international proficiency panels. NVSL is planning to take five Australian quality control testing panels in FY 2001. Included are serum panels for a number of diseases that are tested for when animals are imported. NVSL anticipates that by FY 2004, it will participate in a minimum of 9 international panels per year which will certainly give VS additional credibility in regards to its ability to safeguard the U.S. livestock industries.

✓ Global animal health intelligence

Veterinary Services obtains global animal health information via a number of mechanisms. OIE member reports detailing current animal health events are received and distributed by the Chief Veterinary Officer as well as accessed through the OIE web page. International Services personnel stationed overseas share animal health information for their region with VS. VS' Center for Emerging Issues utilizes a data mining tool to rapidly scan electronic information for global and domestic animal health information. In addition, a liaison position located at the Armed Forces Medical Intelligence Center taps into AFMIC's global information. Personal contacts developed internationally by scientists at all levels within VS also provide information on animal health events around the globe.

The information obtained through these mechanisms is assessed, analyzed, and processed into useful information for decisionmaking. Impact worksheets are prepared for new occurrences of significant diseases by VS' Center for Emerging Issues. These impact worksheets examine the affected country's production and trade in potentially infective products, potential U.S. exposure, and trade implications. Other briefing papers are prepared by Animal Health Programs staff and others to inform U.S. decisionmakers of the potential significance of an event and of proposed U.S. responses.

During FY 2002 through FY 2004, a number of improvements will be implemented: a Lotus Notes Country Database being developed by VS in collaboration with other APHIS units will be made fully functional by FY 2002. This database will provide a vehicle for VS, IS, and other APHIS personnel to share current information on a country by country basis. Methods for anticipating global animal health events will be explored by CEAH during FY 2002 - FY 2004.

✓ **Risk assessment**

Areas of emphasis include assessing: 1) the probability of exposure of domesticated livestock to foreign animal diseases should incursions into the United States take place, and 2) the consequences of foreign animal diseases in the United States. Exposure and consequence assessment are components of risk assessment identified in the WTO-SPS Agreement and in the Office International des Epizooties (OIE) risk analysis code. The increased emphasis on exposure and consequence assessment may require greater interaction among field personnel, headquarters staff, and analysts at the Centers for Epidemiology and Animal Health in acquiring and refining data regarding livestock populations, industries, and exposure pathways in the United States.

1.2 Cattle Ticks

The goal of the Cattle Fever Tick Program is to prevent establishment of cattle fever and its vector, the cattle fever tick, in the continental United States. Currently, a number of factors including funding, climatic conditions, animal hosts, and pesticide restrictions raise concern for the program's future viability.

There has not been a freeze south of Laredo for the last five years. A freeze situation reduces off-host populations of ticks. Also, there has been a persistent regional drought resulting in higher livestock concentrations, and higher tick infestations along the Rio Grande River in Mexico, facilitating the movement of cattle ticks into the U.S.

Infestation rates on apprehended Mexico livestock have risen from 10 percent in the 1970's to over 90 percent in FY 2000. In addition, free-ranging wildlife may facilitate the movement of ticks from Mexico and act as carriers of the ticks in vacated pastures.

Finally, the chemical of choice for cattle fever tick control, coumaphos, is under continuing review by EPA. No effective alternative to coumaphos exists. Potential new products or new methods of application developed by ARS for control of fever ticks on wildlife cannot meet FDA/EPA requirements for field use, even for restricted use by USDA personnel in an invasive species eradication program. Increasing data requirements required by EPA and FDA have discouraged the pesticide industry from pursuing new products for the livestock industry because the high costs of providing those data sets ($30 - $40 million) exceeds the perceived market.

1.3 Emergency Management

VS continues to prepare for potential incursions of high risk diseases. An overall response plan covering all list A diseases as well as other high risk diseases will be developed. The Australian AUSVETPLAN model is being used as a guide. The parts of the AUSVVETPLAN Model VS is using are 1) Disease Strategies, 2) Operational Procedures, and 3) Enterprise Specific Issues. The disease strategies covers the list A diseases described by OIE. Our concept is to develop a strategy that covers all list A disease plus other disease agents that fall into similar categories but are not on OIE's list. This strategy will assure that the US is prepared to respond to an unknown etiology before lab diagnosis and once the etiology is laboratory confirmed a more focused

strategies can be used. Our plan will also cover issues which cross all diseases such as communication, disposal, euthanasia, decontamination and compensation. During this process we will identify specific issues that will need to be addressed either as policy or needed research. The response plan will identify and integrate responsibilities, roles, authorities, and resources to permit all Federal, State, and industry partners to be properly prepared.

VS also continues to strengthen the partnership among International Services (IS), Plant Protection and Quarantine (PPQ), and VS, so as to streamline the coordination of information, operations, and policies. This coordination should lead to earlier identification of potential threatening situations. VS is also working with the Agricultural Research Service (ARS) to develop a closer working relationship with the Department of Defense, the Federal Bureau of Investigation, and the Central Intelligence Agency to be better prepared to minimize the risk from and respond to potential bioterrorist activities.

VS also continues to develop and implement emergency management educational curriculum to improve the skills of Area Veterinarians and other APHIS personnel. The curriculum will also be offered to State Veterinarians and other State personnel. This curriculum will expand training beyond a focus on foreign animal diseases to also include emerging diseases, bioterrorism, media relations, etc. The curriculum will be finalized in FY 2001.

1.4 Nonindigenous Invasive Species

A new staff will be created within AHP to address nonindigenous invasive species. Training programs will be developed and implemented for port inspection personnel that specifically target detection and methods to prevent entry of invasive species that threaten animal agriculture. An aggressive public education campaign to convey the risks and control requirements associated with invasive species that threaten the U.S. animal agriculture industry will be undertaken. Outreach programs, such as a separate web site to disseminate information to the industry, State and local governments, and the public will be developed. Meetings with stakeholders, industry, and consumers will be held to increase awareness of the potential harmful effects of invasive species. Methods to research and identify potential invasive species and their pathways of introduction into the U. S. will be developed. Risk analyses processes will be used to determine the potential environmental and animal and human health damage levels associated with identified invasive species. VS will also assist other agencies and headquarters' units develop emergency management and eradication strategies for those invasive species found established in the U.S.

Goal 2 - Monitor the health and productivity of U.S. animal populations and monitor the health-related attributes of animal products and biologics.

2.1 Emergency Management System

Throughout FY 2001 to FY 2004, VS will continue to strengthen partnerships and networks. VS will improve its working relationships within and between its four principle partners; Federal agencies, State agencies, the animal industries, and private practitioners involved in the veterinary profession. VS will also expand detection training beyond Federal and State veterinarians to

include private practitioners, and as appropriate, producers. Using multiple techniques VS will help States and Territories meet the Standards for State Animal Health Emergency Management Systems.

VS will also enhance monitoring, surveillance, detection, and diagnostic capabilities with new technologies and approaches, such as text-mining software, to fill in the gaps in current domestic monitoring and surveillance systems.

2.2 Biologics

An adverse event is defined as any undesirable and unintended occurrence after the use of a biological product, whether or not the event was caused by the product. For products administered to animals, adverse events are those involving the health of the treated animal, including the apparent failure to protect against disease. For products intended to diagnose disease, adverse events refer to anything hindering the correct diagnosis.

Draft *Guidelines on Pharmacovigilance of Veterinary Medicinal Products: Management of Adverse Event Report* were published in the Federal Register. This draft was developed by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH is a committee consisting of representatives from the U.S., Japan and the European Union (EU), both from the regulatory and industry perspective.

The international document on pharmacovigilance will be used as a final guidance document by U.S. veterinary biologics licensees, permittees, and applicants in conjunction with new Federal rules and regulations for adverse event reporting (vaccinovigilance), currently under review within the Agency. A Biologics Epidemiologist and staff will be hired to develop and manage the national vaccinovigilance program within the Center for Veterinary Biologics.

The information from this vaccinovigilance program will enhance CVB's ability to take regulatory action expeditiously and in a more uniform manner. This information could also become a significant feedback loop to assist CVB in resource allocation concerning product inspection (testing of products prior to release). Ultimately it would be an informational database for CVB concerning licensure of like products. CVB would have an understanding of baseline reactions or known events concerning a type of product and appropriate information could be provided to the end user to allow for a more informed consumer.

2.3 Diagnostics

Surveillance for various disease entities is an important mission for VS. However, these surveys can be very expensive and time-consuming. It is important for NVSL to assess where potential changes can be made in these surveys to improve their quality. NVSL is tracking improvements in the quality of surveillance testing with quality being measured by increased accuracy, decreased turnaround time, or decreased cost. By FY 2004, NVSL expects to be able to demonstrate quality improvements in some of the surveys it participates in.

2.4 Surveillance

✓ BSE

The worldwide BSE landscape changed significantly at the end of 2000. Findings of native BSE cases in Germany, Spain, and Italy raised questions about the ability of the European Union to enforce measures put in place to prevent the spread of BSE. This concern regarding enforcement also suggests that, in addition to European countries, other countries around the globe that accepted live ruminants and ruminant products from Europe during the last decade may be at higher risk of exposure to the BSE agent than previously thought.

VS continues to take actions to prevent BSE from occurring in the U.S. and to minimize the impact if it were to occur. New restrictions on feed materials from Europe were imposed at the end of 2000, additional restrictions may be put in place on imports from other countries as more information is obtained about their exposure to European products. Within the U.S., BSE surveillance remains a priority. While the U.S. more than meets the OIE surveillance goals as a nation, there are geographical regions within the U.S. in which surveillance could be enhanced. A focused effort to improve this regional surveillance is being undertaken. In addition to cattle showing CNS signs, a priority is being placed on sampling downer cows. Research has shown that the downer cow population is a very good target population for BSE surveillance. This population includes animals which might be exhibiting subtle CNS signs as well as those that might have injuries secondary to incoordination due to BSE.

✓ bovine tuberculosis

TB has an important worldwide impact on animal industries and human health. Control measures are based on prevention and eradication. Surveillance is a key element for management of prevention and control programs. The objective of the TB program is to reduce the prevalence and transmission of the disease until it is eradicated from this country so that it no longer poses a threat to livestock, wildlife, and public health.

Surveillance for TB serves the purpose of enabling VS to obtain an accurate picture of the course of TB in an area over time and permits timely interventions if the trend observed deviates from what is expected. Bovine tuberculosis is a national program disease that requires the reporting of all suspected tuberculosis cases by producers, veterinarians, slaughter establishments, and diagnostic laboratories. Routine surveillance activities include passive reporting of suspected TB cases by veterinarians and diagnostic laboratories, results of show or exhibition TB test requirements, and change-of-ownership testing. Active surveillance includes collecting and analyzing data on tissue samples, animal testing, inspection reports, and test outcome reports for point concentration monitoring from cattle, bison, goats, and captive cervids at slaughter, interstate movement testing establishments, and Pasteurized Milk Ordinance Testing in dairy cattle. Currently, slaughter surveillance for cattle is inadequate to meet the surveillance needs of cattle species. Outbreak surveillance will be conducted in high incidence States via on-farm wide area testing programs and trace testing programs related to movements of infected animals.

Sentinel Surveillance through annual herd testing will be increased through encouraging the establishment of more accredited herds.

✓ **brucellosis**

Brucellosis has an important worldwide impact on animal industries and human health. The objective of the national brucellosis program is to eradicate the disease from this country so that it no longer poses a threat to livestock, wildlife, and public health. Surveillance is a key element for all disease eradication programs. Surveillance for brucellosis serves the purpose of enabling VS to detect newly affected herds rapidly before the disease is allowed to spread. Surveillance needs and options for brucellosis must be flexible allowing changes as the disease situation and risk of infection change.

Enhanced surveillance will be critical for a minimum of 5 years after the U.S. is declared free of brucellosis. Continued surveillance after the 5 year period will be required at some level to ensure that the U.S. remains brucellosis free. Generally, after a state or country has been declared brucellosis free there is a push to drastically reduce surveillance activity for the disease. Frequently, the issue involves the economics of conducting surveillance for a disease no longer thought to exist and concerns regarding the necessity of maintaining surveillance after a state or country is declared free of a disease. The challenge will be to ensure that surveillance will not only be economically feasible, but will be effective as well. Surveillance will need to be monitored continually to assess effectiveness, as well as to determine when surveillance may need to be altered as requirements change. It is important to recognize the need for continued surveillance to ensure the disease does not reappear and to confirm that the United States remains free of the disease.

Through the National Brucellosis Program, mandatory surveillance for the disease will be maintained by requiring immediate reporting of all suspected brucellosis cases by producers, veterinarians, and diagnostic laboratories to state veterinary authorities. Sentinel surveillance programs for brucellosis will be maintained through voluntary annual herd testing of Certified Brucellosis Free Herds that are certified for 12 month periods. Routine passive surveillance will continue with intrastate and interstate change-of-ownership testing, show/exhibition testing requirements, and laboratory testing for disease diagnosis in cases characterized by abortion, retained placenta, or impaired fertility, or orchitis and infection of the accessory sex glands in males. Routine active surveillance activities include first point concentration testing of swine and bovine animals at auction markets in high risk areas. Nationally, more emphasis is being placed on collecting and testing blood samples from bovine animals at slaughter establishments. As slaughter markets are further consolidated, emphasis in sample collection and testing will focus on livestock transportation patterns and determined levels of disease risk. Improved quality control and refinement in methods for collecting blood samples and animal identification devices at slaughter will provide more accurate levels of detection of any new reemergence of the disease. Improved collection methodologies will also allow better animal tracing during epidemiological investigations. Additionally, Brucellosis Milk Surveillance testing using the Brucellosis Ring Test (BRT) will continue for all dairy herds in the United States as part of the Pasteurized Milk Ordinance Section 7, Animal Health. In the event there is an outbreak of brucellosis, outbreak

surveillance actions will be initiated in the form of area testing programs to collect and test blood samples from bovine animals.

✓ **chronic wasting disease**

Chronic wasting disease (CWD), a transmissible spongiform encephalopathy of deer and elk, was identified in the U.S. farmed elk industry in 1997. APHIS surveillance for CWD in farmed cervids in FY 1998 and 1999 totaled 692 animals. Surveillance in farmed elk in FY 2000 totaled 1,469 animals. Uncertainty regarding the fate of positive herds has contributed to reluctance on the part of producers to participate in surveillance or report the possible presence of this disease in their herds to date. Because of the lack of reporting and surveillance, the prevalence of CWD in the farmed elk industry is unknown, compromising efforts to control the spread of disease. In FY 2001, the goal is to double the number of animals tested. In FY 2002 a CWD herd certification program for farmed elk will be in its first year and it is hoped that surveillance numbers will begin to increase quickly. Surveillance will be the cornerstone of the certification program, with herd status based on the number of years of surveillance with no detection of disease. Currently, the only reliable test available is immunohistochemistry of the brainstem, a postmortem test. If alternative tests become available, particularly ones that may be used in live animals, surveillance strategies and projected numbers may change.

✓ **classical swine fever**

In FY 2000, 80,000 samples were submitted with negative CSF test results. At the end of FY 2001, CCC funds for testing will be exhausted, however, sample submission will continue while additional funding is being identified. A new CSF strategic surveillance plan will be developed in FY 2001. Three possible components of the surveillance plan are: a nationwide random selection sampling of commercially slaughtered cull boars/sows, intensive sampling of high risk herds (i.e. garbage feeders, small slaughter houses) in high risk states (including Puerto Rico), and random sampling of commercially slaughtered feral swine. The new surveillance plan will be implemented in FY 2002.

✓ **equine infectious anemia**

Equine infectious anemia (EIA) is an infectious disease of horses caused by a lentavirus, (equine infectious anemia virus (EIAV)). It is not a zoonosis. Transmission between horses in close proximity is by large biting insects, such as horse flies and deer flies (tabanids). Rarely it is transmitted iatrogenically. In most countries EIA is a notifiable disease. Overall EIA does not have an important worldwide impact on animal industries. Surveillance is a key element for management of prevention and control programs.

The objective of the EIA program is to detect the disease in all equine populations, and reduce the prevalence and transmission of the disease so that it no longer poses a threat to equine in this country. Detection of EIA in equine is accomplished through immunological testing of blood samples. Effective control measures for EIA are based on prevention and eradication. The increased level of EIA surveillance will serve the purpose of enabling Veterinary Services to

obtain an accurate picture of the prevalence of EIA in the equine population, track the course that new outbreaks of EIA might take in an area over a given time, and permit timely interventions when the trend observed deviates from what is expected.

✓ **Johne's**

Johne's disease is an endemic disease in the US. The NAHMS Dairy study in 1996 estimated that 10 percent of U.S. dairy cattle and 20 - 40 percent of U.S. dairy herds are infected. The challenge of finding positive animals within a herd is the stigma attached to infected herds and the fear of regulatory involvement. A national education campaign has been initiated by both the beef and dairy industry to get producers to recognize that Johne's is a management disease and that it can only be effectively controlled at the farm level. This concern of regulatory involvement along with the expense of diagnostic sampling, inhibits testing by the producers. Because of these issues, the Johne's program is voluntary.

Since the Johne's program in voluntary at both the producer and state level, a surveillance system needs to be developed to objectively collect prevalence information. In FY 2001, a surveillance system to monitor the level of disease will be devised and will be established in FY 2002. As testing methods are improved to allow more rapid and reliable testing and as information is gained on the prevalence of Johne's disease, the number of animals and herds to be sampled will be refined. By FY 2004, at least 600 herds will be sampled.

✓ **pseudorabies**

Control measures for pseudorabies in the United States are based on detection, prevention and eradication. The objective of the national pseudorabies eradication program is to find existing cases, and reduce the prevalence and transmission of the disease until it is eradicated from this country so that it no longer poses a threat to swine in this country or to our international markets. Surveillance is a key element for management of prevention and control of this program. Surveillance for pseudorabies serves the purpose of enabling VS to obtain an accurate picture of the course of pseudorabies in high risk areas over time and permits timely interventions if the trend observed deviates from what is expected. Surveillance for pseudorabies in swine is part of a national program disease that requires the reporting of suspected cases by producers, veterinarians, slaughter establishments, and diagnostic laboratories. Routine surveillance activities include passive reporting of suspected pseudorabies cases by veterinarians and diagnostic laboratories, results of swine livestock show/exhibition test requirements, and change-of-ownership testing. Active surveillance includes collecting and analyzing data on slaughter blood samples, farm testing, market inspection reports, test outcome reports for point concentration monitoring of swine at slaughter establishments, and interstate movement testing. Currently, slaughter surveillance for breeding swine is inadequate to meet the surveillance needs to assure freedom from disease by the swine industry. Outbreak surveillance will be conducted in high incidence States via on-farm wide area testing programs and trace testing programs related to movements of infected animals that must be traced and origin herds tested. Sentinel surveillance through annual herd testing will be increased through encouraging the establishment of more accredited herds.

The success of pseudorabies eradication efforts is dependent on finding all remaining undetected pseudorabies infected herds. To accomplish this, surveillance needs to be increased in two areas, 1) cull sow and boar testing at slaughter and 2) development of a practical way to test "finishing" hogs at slaughter. The goal is to increase cull sow and boar testing so as to survey 20 percent of the national swine breeding herd annually rather than the 10 percent that are being surveyed annually at the present time. The nation's swine breeding herd fluctuates between 6-7 million head. Approximately 40 percent of that total are culled each year. Not all cull breeding swine are individually identified. This lack of identification in cull sows and boars at slaughter has been a limiting factor for surveillance efforts; animals must be able to be identified to the farm of origin in order for test results to be useful. However, if cull animals are sent to slaughter in lots, killed together, and identified back to the last premise of origin, then the goal of testing 20 percent of the swine breeding herd can be achieved by testing 50 percent of these animals at slaughter without individually identifying each animal. In addition, collection should occur at all slaughter establishments; currently there are some slaughter establishments that are not participating in surveillance.

A pilot study is now underway in Iowa to study the feasibility of doing slaughter testing of "finisher" swine. This test will be used on meat from identified lots of slaughter swine. Positive samples will be traced back to the farm of origin and further testing conducted on the identified farm. If a positive herd is disclosed by this testing, then further surveillance will be conducted around the affected herd and in any herds tracing to or from the affected herd.

- ✓ **scrapie**

In FY 2000 APHIS started live animal testing as part of the test validation project. This testing will be expanded once the test is approved and regulatory authorities are in place to include all scrapie exposed animals.

Slaughter testing will start in FY 2001. Low level sampling will be maintained until adequate identification is in place to determine prevalence on a regional basis. Once adequate identification is in place, 1,000 animals will be sampled at slaughter per month for one year to determine prevalence. If this methodology is demonstrated to be effective VS will target the testing to maximize its usefulness for locating infected flocks and increase sampling to up to 8,000 samples per month by FY 2004.

The number of samples from slaughter versus live animal sampling will be determined based on which method is more cost effective in disclosing new infected and source flocks. VS will also encourage producers to submit found deads over 18 months of age for sampling. Sampling of all suspect animals at necropsy will continue. The number of animals sampled will be reported by NVSL.

- ✓ **swine health protection**

Historically, swine have always been valued for their ability to recycle food waste. However, because it is not permitted in many states, today there are few remaining commercial garbage and food waste feeders in the U.S. The increased tonnage of food waste that is not being used for feed is becoming an environmental issue as well as a disease control issue. For swine to be safe "recyclers", it is necessary to continue to enforce the Swine Health Protection Act to ensure that the food waste being fed does not pose a risk of disease transmission. To more efficiently treat the tons of food waste for animal consumption, new technologies are being developed to safely convert food waste into a safe, nutritious animal feed at central locations. The authority to implement newer technologies will be added to the current regulations through the rulemaking process. VS is in the process of changing 9 CFR 166 to allow licensing of facilities that process food waste with new technology that is equivalent or superior to treatment by boiling for 30 minutes. Food waste treated in this way can then be transported to other locations for blending or fed directly to livestock of different species including swine. The requirements of the Swine Health Protection Act can be more accurately monitored at these central locations. The finished product is safe and has a long storage life. A panel of experts will be named to approve requests to use new technologies. VS and/or state authorities will be responsible for inspection. Swine on premises that use food waste (garbage) feeding programs but do not utilize newer technological methods to adequately treat food waste continue to be a disease threat to the U.S. swine industry. This type of garbage feeding operation must continue to be monitored on a risk-based inspection process. Higher risk premises must be involved in a swine disease surveillance program that involves regular monitoring and documentation of herd health status. In addition, classical swine fever surveillance should be increased in identified high risk geographical locations where garbage may be fed to swine. These include, the Texas-Mexico border area, air and sea ports in south Florida, the territory of Puerto Rico, and the areas that have a lot of international traffic such as military bases and international air cargo centers. This program requires continuous monitoring of potential sources of international food waste.

2.5 National Animal Identification System

In partnership with industry and State governments, VS intends to develop a reliable and cost-effective system of animal identification for use in the United States. The system will be developed by FY 2001 and fully implemented by FY 2004. Animal identification systems must be able to demonstrate the ability to adequately trace the movements of individual animals, complement agency programs and support the agency mission. Developing national standards includes: 1) a uniform, internationally recognizable numbering system for individual animal identification, 2) a uniform premises identification system, 3) a method to evaluate and approve identification methods for official use in livestock, 4) a list of basic information necessary to adequately trace animal movements, 5) official use of electronic identification in cattle, and 6) standards for electronic data collection and retrieval of information necessary to support agency goals.

2.6 Emerging Animal Health Issue Detection

Detecting emerging animal health issues requires a variety of approaches. Field investigations for foreign animal disease events may uncover emerging animal health events. Specialized surveillance systems including sentinel farms, practitioner/laboratory networks, and data mining techniques are also useful for detecting emerging animal health events. Events may also be identified as scientists, producers, and animal owners share information regarding the appearance of unusual clinical signs.

In 1999, a VS working group examined VS' handling of emerging animal health events. The working group identified a number of weaknesses in VS' current handling including: 1) data collection is not systematic, 2) reporting lines are unclear, 3) no central coordination and comprehensive analysis, 4) little differential diagnosis follow-up, 5) immature surveillance systems, 6) worldwide data sources overlooked, 7) reluctance to look into issues, 8) lack of clarity about decision making, and 9) the only emerging issues being addressed are emergencies.

During FY 2002 through FY 2004, VS will undertake a number of activities to resolve these weaknesses. During FY 2002, VS will finish the implementation (begun in FY 2001) of a centralized reporting and tracking system for emerging animal health events. Key components of the system for data collection will be: 1) a Lotus Notes Database (which parallels and interfaces with, but does not replace the foreign animal disease investigation database), 2) an 800 number, and 3) an email box. APHIS personnel will report unusual situations or potential emerging animal health events into this centralized system. A VS memorandum specifying procedures for the Emerging Animal Health Issues Tracking System will be issued in FY 2001. VS' Center for Emerging Issues will monitor the tracking system and conduct initial assessments of items entered into the system as appropriate. For issues not dealt with at a local level, the VS Emergency Management Leadership Team will coordinate additional assessments as needed and act as a decisionmaking body for determining an appropriate response to emerging animal health situations. During FY 2003 and FY 2004, expand the Emerging Animal Health Issues Tracking System to allow groups/individuals outside of APHIS to report emerging situations. During FY 2003, develop procedures for periodic trend analysis of the data collected by the Emerging Animal Health Issues Tracking system, and begin implementing such analysis. Periodically report the findings from this trend analysis. In addition to the Emerging Animal Health Issues Tracking System, during FY 2002, pilot tests will begin of new emerging issue detection processes, such as those recommended by the Swine Futures Team, for example, practitioner and laboratory-based reporting systems.

2.7 Monitoring and Surveillance Initiative

VS animal health surveillance programs target individual livestock species for specific infectious/contagious disease agents. In this regard, VS must use multiple surveillance systems in its efforts to effectively control, eradicate, and prevent animal diseases in this country. Furthermore, these must be in concert with the Agency's epidemiological delivery system. Comprehensive surveillance systems require interconnected elements and activities that contribute

to the achievement of program objectives and link animal health officials and livestock industries at local, state, national, and international levels. Surveillance system design must be organized in terms of structure, process, and output with enough flexibility to allow for qualitative modifications to be made as necessary to enhance overall performance. Surveillance priorities must also be appropriate to the disease epidemiology, infrastructure, and resources available. Surveillance systems used for national animal disease programs should be in line with state and regional surveillance plans and support U.S. international trade goals. The VS goal for animal health surveillance includes an integrated approach to coordinate and streamline surveillance activities at both the State and Federal level.

In FY 2000, a VS working group defined a base framework for a comprehensive and integrated animal health surveillance system. The system was based on recommendations from the swine futures project, the Estes Park meeting on surveillance in 1998, and other sources of information. The group determined that the issues are complex and it is difficult to reach consensus.
In FY 2001, there will be a concentration of FY 2000's efforts and model on a more specific situation, the surveillance efforts for swine, namely pseudorabies, brucellosis, and hog cholera (classical swine fever). Surveillance needs, activities, and performance will be analyzed in light of integrating and streamlining systems as much as possible. Recommendations will be made. Especially important will be meeting the following objectives of surveillance as outlined by the 2000 working group: 1) to rapidly detect and respond appropriately to introduced and emerging diseases, 2) to promote the safe international trade of animals and their products - safeguarding, 3) to facilitate efficiency and streamlining of current eradication/control programs, and 4) to improve knowledge of animal health in the US among health professionals, producers, and the general public.

In 2002, the recommendations of the 2001 swine initiative will be evaluated in light of their implementation by federal-state-industry people in the field. This evaluation would involve input from CEAH, Staff, VS field, State, and Industry. Adjustments to the swine model for integrated surveillance will be made. Adaptation of the swine model for other species of livestock will begin. This adaptation will be a cooperative effort among CEAH, Staff, and field personnel as well as State and livestock industry people and will continue into 2003.

2.8 National Animal Health Monitoring System

The National Animal Health Monitoring System (NAHMS) is one of the tools APHIS uses to organize and develop data sources to address issues facing U.S. animal agriculture. NAHMS uses data sources from Federal and State animal and public health agencies, universities, diagnostic laboratories, producer groups, and private interest groups. The program serves as the impetus for Federal, State, industry, and university collaborators to gather health information on national animal populations and to conduct multiple ongoing and targeted studies where a need for additional data is indicated.

A NAHMS program review was initiated in 1999 using a non-traditional approach. Representatives of various customer groups within American and international animal agriculture collected input to guide a review panel in developing recommendations to be incorporated into the

design and completion of our programs. Ultimately, the panel encouraged NAHMS to increase its focus on animal health issues with broad public implications while continuing to lead VS into areas outside of its traditional service, such as food safety, antimicrobial resistance, environmental health, and public health. The panel recommended that greater flexibility be designed into NAHMS studies to permit the dedication of resources to target disease-specific studies and to help VS address "hot" issues. One outcome of the review was a challenge to conduct customer needs assessments to produce products that will serve VS, as well as external, customers. NAHMS staff are committed to solicit and incorporate suggestions for design and completion of studies from VS' field, regional, and Riverdale staff members. One project goal is to assist VS in integrating monitoring and surveillance activities. To date, NAHMS national projects have analyzed different animal commodities and populations on a 5-year cycle. In 2001, NAHMS will determine whether that rotation system should be maintained and/or whether the time between reviews should be lengthened, or whether a different system is needed to assign resources effectively to the US' various animal industries, and to serve the needs of VS programs and monitoring and surveillance activities. The review panel also encouraged NAHMS to explore opportunities to serve non-traditional livestock industries and to increase utilization of alternative funding resources.

Plans for FY 2002-FY 2004 include: complete the dissemination of results from the NAHMS Swine 2000 and Sheep 2001 national studies; implement a national study of the dairy industry including features not present in previous NAHMS studies; and conduct additional projects identified under a long-term plan to be released in late FY 2001. Examples include: plan additional focused national studies as indicated; expand ongoing monitoring projects, such as the current National Animal Health Reporting System (NAHRS); explore opportunities for sentinel monitoring systems, such as the regional Bluetongue Surveillance Pilot Project initiated in FY 2001; conduct specific targeted studies, such as the national scrapie prevalence study, the scrapie third eyelid test validation project (a joint effort wiht ARS), serologic test quality control monitoring for the national voluntary Johne's herd status program, and several national Johne's pilot project studies; and explore options to expand service to non-traditional animal agriculture and wildlife industries and to provide a proactive view of health issues facing VS and US agriculture.

Goal 3 - Enhance the health status of U.S. animal populations by anticipating and responding to new or emerging threats and by managing, controlling, or eradicating those already identified.

3.1 Emergency Management System

Throughout FY 2001 to FY 2004, VS will continue to build a national preparedness and response infrastructure in concert with its Federal, State, and industry partners.

VS will continue to help each State build their emergency management systems throughout FY 2001 to FY 2004 by: continuing to develop common standards for coordinated action among the States without compromising each State's unique system of emergency management;

supporting States and Territories in meeting agreed upon standards; working with State agencies to begin to clearly identify emergency management responsibilities within their respective Departments of Agriculture; and by working with Emergency Management Agencies and professionals to develop a closer working relationship with Sate Departments of Agriculture (health officials) and State emergency management organizations.

VS will build on their cooperative partnerships with industry throughout FY 2001 to FY 2004 by working with animal industry groups to begin to raise the priority given to emergency management within their respective industries and identify State or regional coordinators to work closely with their respective State agencies. VS will also work with the American Veterinary Medical Association to identify a more active role for their emergency response teams and accredited veterinarians.

Throughout FY 2001 to FY 2004, VS will improve on their own emergency management system by: utilizing modern communication technology to improve the preparedness and response capabilities of APHIS; focusing budget and planning activities on issues that pose the highest risk and seek additional funding as necessary; clarifying the roles and responsibilities between and within VS National staff and field operations; and strengthening communication links with PPQ and IS. As part of the improved emergency management system, VS will develop and implement plans for a secure National Animal Health Emergency Management Coordination Center in Riverdale, Maryland, with a full complement of scientific and technical support from the Emergency Programs Staff. They will also develop and implement plans for two completely staffed and trained Regional Emergency Animal Disease Eradication Organization units capable of fully addressing an impending and actual ongoing animal health emergency in the field, with the capability to effectively interact with the Emergency Programs Staff in Riverdale, Maryland.

The animal health community must become a more integral part of the nation's overall emergency management system. These relationships are essential to bring about the organizational, educational, and financial infrastructure necessary to support a world-class animal health emergency management system.

3.2 Brucellosis

The first State-Federal cooperative efforts towards eradication of brucellosis caused by *Brucella abortus* in the United States began in 1934 as part of a recovery program to reduce the cattle population during severe drought conditions. A number of states saw this as an opportunity to reduce losses due to brucellosis. In 1934 and 1935, the reactor rate in adult cattle tested was 11.5 percent.

The magnitude of the brucellosis problem in the United States in terms of economic impacts to the cattle industry and human health prompted Congress, in 1954, to appropriate funds for a coordinated national effort to eradicate brucellosis. The eradication program was designed as a cooperative effort between the federal government, the state, and the livestock producers. Since its inception, the brucellosis eradication program has undergone many modifications that have

allowed it to progress significantly. It is anticipated that the goal of eliminating brucellosis from cattle and captive bison and captive cervids will be reached by FY 2003.

VS will build on the successes of the eradication of brucellosis from U.S. cattle and captive bison and cervids with the eradication of brucellosis from domestic swine by 2004, by preventing the transmission of brucellosis from other species to domestic livestock, and by making progress towards the eradication of brucellosis in other species (feral swine, caribou/reindeer). VS will also make progress towards developing a plan for the eradication of brucellosis from bison and elk in the Greater Yellowstone Area. A Record of Decision regarding bison in the Greater Yellowstone Area was reached in December 2000.

3.3 Tuberculosis

APHIS will eradicate bovine tuberculosis through four major strategies: 1) eradicate tuberculosis from the remaining pockets of infection in the domestic livestock populations, 2) eradicate tuberculosis from the wildlife population in order to prevent transmission of the disease from wildlife to domestic livestock, 3) increase laboratory and diagnostic support to increase testing capacity and to incorporate new methods and technology, and 4) implement increased levels of surveillance to ensure that unknown or new incidences of tuberculosis can be eliminated before they spread.

The Bovine Tuberculosis Eradication Program works cooperatively with the state animal health agencies and the national livestock industry to achieve the eradication of bovine tuberculosis from domestic livestock in the United States, and prevent its recurrence through continued disease monitoring and surveillance and safe import policies. Program activities include conducting investigations for tuberculosis on livestock herds identified through slaughter surveillance, tracing exposed animals moving from infected herds, testing possible source herds for infections, and conducting area tests. Infected herds are depopulated when feasible. For those herds that cannot be depopulated, test and slaughter procedures are implemented to free those herds of tuberculosis. The program also includes oversight of state programs for state designations of modified accredited or accredited free, training in tuberculosis epidemiology and eradication procedures, and certification of veterinarians to conduct tuberculosis tests.
The most significant issue facing the Bovine Tuberculosis Eradication Program today is the endemic foci of bovine tuberculosis in free-ranging white-tailed deer in Michigan.
Mycobacterium bovis in free-ranging white-tailed deer in Michigan has been linked to at least 9 outbreaks of bovine tuberculosis in domestic livestock. Wild animal surveys have been conducted and extensive surveys are being planned. Extensive area testing of domestic livestock will continue. This testing may eventually involve the entire state and possibly surrounding states.

The inability to depopulate large *M. bovis*-infected dairy herds or free them of disease also has been an important deterrent to tuberculosis eradication in the United States. At best, VS has been able to limit the disease to a few herds. However, if one (or more) of these herds had been (or does become) dispersed following quarantine release, tuberculosis-exposed cattle could be widely distributed throughout the dairy herds of the Midwestern and Western United States. In all there

are approximately 10,000 exposed cattle in two herds, plus an additional 20,000 cattle in similar herds that have been released from quarantine but are expected to break again with tuberculosis.

3.4 Pseudorabies

The immediate concern for pseudorabies eradication is the completion of the program in Iowa. The rest of the nation has nearly completed eradication with only three known infected herds in January 2001 - 1 each in Indiana, New Jersey, and Tennessee. Iowa has embarked on a massive testing program that includes two tests on all premises in the Stage II area and 1 test on all premises in the Stage III are during CY 2001. All herds or premises in the entire State are mandated by State law to vaccinate all swine for pseudorabies and to maintain vaccination schedules at four times per year for breeding swine and one time for all "finishing" swine. It is essential that adequate regulatory personnel be available to see that these measures are enforced and completed. By 2004 it is anticipated that Iowa will have completed the program.

A National Feral/Wild Swine Action Plan was proposed in June 2000 to address the issue of feral/wild swine and disease risk. The proposed action plan outlines an approach for establishing a feral/wild swine program in the U.S. and its territories. Components of the program would reside with APHIS, other components would reside with other federal and state agencies. A committee is to be designated to develop Uniform Methods and Rules for managing feral/wild swine in areas where they exist.

3.5 Scrapie

All known infected and source flocks will be on flock plans or under movement restrictions by FY 2002 and the percent of scrapie infected or source flocks removed from infected or source flock status or on flock plans will be increased from 29 percent in FY 1999 to 95 percent in FY 2004. All 50 States have agreed to be consistent with federal regulations requiring that all infected and source flocks be placed under movement restrictions. Any State that fails to place all infected and source flocks under restriction will be removed from the consistent State list. These percentages will be calculated using the status information reported in the GDB. All Area Offices will maintain complete and accurate information in the GDB for all source, infected, exposed, non-compliant, and participating flocks and for all tested, suspect, exposed, and high risk animals.

3.6 Poultry Initiatives

✓ Avian Influenza

Subtype H5 and H7 low pathogenic avian influenza (LPAI) viruses are a threat to domestic poultry populations because of the potential for these viruses to become highly pathogenic. H7 LPAI virus infections have been present in the live bird marketing system of the Northeastern United States (centered in New York City) for the past 5 years. VS has developed a Federal-State-industry cooperative program to eliminate these infections from this marketing system. The program will include a thorough study of the epidemiology of these viruses and the use of bird identification in this marketing system; an education campaign on the control and

prevention of LPAI for marketers, dealers, and producers; and the periodic closure, cleaning, and disinfection of markets and other facilities to assist in controlling these viruses.

✓ **National Poultry Improvement Program**

Reduction in Mycoplasma gallisepticum Cases in Turkey Breeding Flocks

Mycoplasma gallisepticum is generally not a reportable disease in most States. Breeders that participate in the NPIP Mycoplasma programs do so on a voluntary basis. Mycoplasma *gallisepticum* is one of the four strains of Mycoplasmas that are recognized as pathogenic to gallinaceous species of poultry. It is commonly designated as chronic respiratory disease (CRD) of chickens and infectious sinusitis of turkeys. It is characterized by respiratory rales, coughing, and nasal discharge, and, frequently in turkeys, sinusitis. Clinical manifestations are slow to develop and the disease has a long course. Air sac disease designates a severe airsacculitis caused by a concomitant infection with a respiratory virus and usually *Escherichia coli.* Airsacculitis in chickens and sinusitis in turkeys can cause significant condemnations at slaughter. MG can be a disease of considerable economic disruption. Since it has been clearly demonstrated that MG is an egg-transmitted pathogen, it is imperative that breeding flocks are negative to prevent the spread to progeny. It is the goal of the NPIP to work with the industry to reduce the number of MG positive turkey breeding flocks through improved biosecurity measures and intensified testing levels of turkey breeding flocks.

Meat-Type Chicken Breeding Flocks in the Salmonella enteritidis Clean Program

Salmonella enteritidis is an egg-transmitted paratyphoid Salmonella that has been shown to play a role in human egg-associated cases and outbreaks of salmonellosis in the U.S. Up to this point, it has been an agent found primarily in commercial laying flocks and some egg-type chicken breeding flocks in the U.S. Because SE is invasive and can result in a systemic infection in chickens and turkeys it has been found in chicken meat in countries outside the U.S. In addition, much of the breeding stock for meat-type chickens originates in the US. It is, therefore, important that primary meat-type chicken breeding flocks are tested free of SE.

SE is not a reportable disease in many States and meat-type chicken breeders participate in the NPIP SE Clean program on a voluntary basis. Efforts are ongoing to get all of the primary meat-type chicken breeding flocks on the NPIP SE Clean program.

Meat-Type Chicken Breeding Flocks in the New Avian Influenza Clean Classification of the NPIP

Highly pathogenic avian influenza is considered an exotic disease in the U.S. Low pathogenic strains of avian influenza are normally handled by State poultry health officials. The Avian Influenza Clean classification of the NPIP was established in an attempt to respond to the Chinese governments requirements for live poultry being shipped into China from the U.S. It is a voluntary program within the NPIP. While the action to include avian influenza into the NPIP had merit, the fact is that several countries make different demands on U.S. poultry breeders with

respect to avian influenza status. These diverse and non-unified requirements has worked against breeders participating in the NPIP avian influenza clean program. It is going to be difficult to obtain wide participation in a voluntary program that has no economic or marketing incentive. It is hoped that the National Center for Import and Export will use the NPIP's avian influenza program as a bargaining chip when negotiating export certificates with our foreign customers.

Salmonella pullorum

There have been no isolates of *Salmonella pullorum* from commercial poultry in the United States since 1991. The total number of isolations has dropped to 3 or fewer in each of the last 9 years. It is hoped that this number will be maintained and hopefully reduced. These isolations occur in small privately held backyard type poultry operations. Eventually pullorum may be eradicated from the United States.

3.7 Johne's

The effort to eradicate Johne's disease will begin with the development of a standardized national program. Program standards for Johne's disease will be put into place in FY 2001. This will allow the individual state programs to be compared. An essential part of the program is the herd status program. These are herds which have tested negative for Johne's disease. These herds are important to the control effort because they identify sources of test negative livestock. Due to the difficulty in detecting *Mycobacterium avium* subspecies paratuberculosis, the organism that causes Johne's disease, the herd status program works to assign levels of risk for infection to the herd. Infected herds that enter into control programs can use replacement animals purchased from status herds. The goal is to enroll a large number of herds into the status program in order to meet the growing demand for test negative replacements. By working cooperatively with state health officials, VS personnel will work to increase the number of status herds through visiting herds that request help, collecting samples for program herds, and developing training programs for producers and veterinarians. At the close of FY 2001, the goal is to have 1,000 herds enrolled in herds status programs with 4,000 herds enrolled by FY 2004.

3.8 Equine Programs

- ✓ **equine infectious anemia**

Work is continuing with state officials to expand disease status from control to eradication as follows: The EIA video-booklet information packet continues to be distributed widely and a 2000 version of the booklet is in production. A bench laboratory guide for 2001 is also in production for the NVSL EIA School. The surveillance program is currently being modified/improved to better interpret the data resulting from a substantive increase in State testing. Early in 2001 VS will host a national EIA conference to address and resolve laboratory-related problems resulting from the increased demand for testing; and as a result of this meeting, it is anticipated changes will be made to the EIA UM&R, VS Memorandum 555.8 and CFR 9 Part 75.4.

✓ **slaughter horse transport regulations/enforcement**

This program is currently fully prepared for implementation with the approval of the final rule. This will be a national program that involves all 50 states and will be monitored using individual equine owner/shipper certificates for every horse that will also be identified using new green back tags. Together this will provide for an effective traceback (to owner) system. Data from owner/shipper certificates and back tags will be entered into a national database program already in place. Data reports will be reviewed weekly and monthly by VS personnel in states where horse-slaughter plants are located (Texas and Illinois.) Training for field VMO's and data-entry has been successfully completed. The introduction of VS field personnel to FSIS colleagues at the slaughter plants has been successful and productive. Managers of the slaughter plants, with help from VS VMOs, will distribute VS educational guidebook to truckers. The educational guidebook includes 1) a video on the program, 2) directories for assistance, and 3) protocol and instructions for completing the owner/shipper certificates.

✓ **APHIS consultation to the BLM Wild Horse and Burro Program (WH&BP)**

More than 45,000 wild horses and burros graze on public lands managed by the United States Department of Interior's Bureau of Land Management (BLM) in the western states. These equids are descendants of animals released or escaped from Spanish explorers, ranchers, miners, soldiers, or native Americans. Congress passed the Wild Free-Roaming Horse and Burro Act of 1971 following a nationwide grassroots effort to protect these animals, which were regularly rounded up by "mustangers" and shipped inhumanely to slaughter. Specifically, this Act mandates the protection, management, and control of wild and free-roaming equids on public lands at population levels that ensure a thriving ecological balance. The BLM manages these equids in 203 herd management areas (HMAs) in ten western states (AZ, CO, ID, MT, NE, NM, NV, SD, UT, and WY). The majority of wild horses are in Nevada and Wyoming. Wild burros are found primarily in southern California, Nevada and Arizona. In addition, there is a large holding area for these horses in Nebraska.

BLM does not have a single veterinarian on its staff; and until recently, it did not have a formal agreement with VS. Since 1999, Veterinary Services has provided complete veterinary consultation on a cost-recovery basis to the BLM WH&BP. While funding is accomplished at the national level through an AD-672, each AVIC is encouraged to work with the BLM State Director to meet the individual needs of the WH&BP in that state.

To date VS VMOs have consulted and participated in the following WH&BP projects: gathers, adoptions, epidemiologic studies, strategic planning, research reviews (existing and proposed), pre-compliance work (training phase), and post-compliance work (training phase). Currently, the program involves teams of VS field VMO's in 26 states, but has the potential to include all 50 states. Each member of this VS team was nominated by their supervisor and selected because of their equine expertise and willingness to work with wild horses and burros. With the WH&BP's plan to significantly increase the number of equids taken off the range in the next five years, the need for the services of VS VMOs is anticipated to increase substantially.

3.9 Chronic Wasting Disease

The goal of the proposed CWD program is elimination of CWD from the farmed elk industry. If CWD is present at only a low prevalence in terms of herd and animal numbers, timely and aggressive action (depopulation of positive herds) may eliminate the disease from the farmed elk industry. Aggressive response in controlling this disease now will decrease the chance of having to deal with a much larger, widespread, and costly problem later. All positive herds that are detected through surveillance will be required to enroll in a herd plan. The preferred herd plan option for positive herds in the current program is depopulation with cleaning and disinfection of the premises. The alternative option is quarantine with continued surveillance and with or without partial depopulation. It is hoped that the difficulties presented by the long term quarantines necessary with this disease will encourage depopulation of most positive herds with the alternative option employed only in circumstances where the producer and state and federal veterinarians and epidemiologists feel that there is limited risk that the disease has spread in the herd.

Herd certification is an important element of the CWD program, requiring long-term, continuing surveillance for all participating herds. Participating herds will be allowed to move animals interstate in trade while nonparticipants will not. Herds will reach the highest herd status after participating in surveillance for five or more years. At the time of publication of this strategic plan the means for tracking herd status had not yet been determined. However, it is probable that this measure will be calculated in the same way as scrapie flock status, with information entered into the GDB by each area office. The goal of the certification program is to have 1,350 herds (75 percent) of optimal enrolled by FY 2004.

Although a line item budget request to support a CWD program has been made in the FY 2002 budget, the requested budget is not sufficient to provide indemnity for the currently known positive herds or for any future CWD positive herds that are detected through surveillance. If compensation is not available to producers with positive herds, there will be limited incentive to participate in the herd certification program and this may compromise success in reaching herd certification goals.

3.10 Wildlife Initiatives

VS' policy is to reduce the risks of disease transmission between free-ranging wildlife and animal agriculture. The translation of this policy into programs and actions depends on current science, risks of transmission, potential economic consequences, and support from industry and the relevant agricultural and wildlife agencies. VS' efforts to control transmission of disease between free-ranging wildlife and animal agriculture are carried out on a cooperative and collaborative basis with respective wildlife agencies. Such cooperation allows VS to contribute to overall wildlife and public health while focusing its program goals. Ongoing and anticipated examples of these collaborative efforts include disease surveillance in wildlife around premises infected with tuberculosis, brucellosis, CWD, etc.; collaborative research on brucellosis on bison and elk in the Greater Yellowstone Area (GYA); and program disease monitoring in wildlife populations i.e., tuberculosis in Michigan white-tailed deer and brucellosis in bison and elk in the GYA. Disease

transmission risks necessitate the establishment of components in VS animal health programs to minimize the risk of transmission. The Wildlife Initiatives also develop agreements with State and Federal agencies dealing with wildlife to prevent the transmission of disease between free-ranging wildlife and animal agriculture. Additional aspects of the Wildlife Initiatives are to conduct applied research on wildlife-domestic animal disease transmission issues i.e., development of oral vaccines for use in bison, cervids, and feral swine, determination of the CWD susceptibility of fallow deer; providing or coordinating diagnostic support for those situations; conducting monitoring and surveillance activities involving wildlife-domestic animal disease situations, i.e. Johnes surveillance in wildlife populations surrounding infected livestock; and providing relevant training to VS personnel, i.e., specialized wildlife training given at least semi-annually to agency personnel.

3.11 Biologics

Pure, safe, potent and efficacious veterinary vaccines and diagnostic test kits protect animal health, which is critical for maintaining a safe food supply and preventing serious human diseases such as rabies. To ensure the purity, safety, potency, and efficacy of vaccines and diagnostics, the Center for Veterinary Biologics (CVB) issues product licenses by establishing standards and reviewing data. These process-control and performance-based systems also support post-licensure measures that monitor the quality of product prepared. Inspection is a process-control system that is transparent, equivalent across the industry and equitably applied to ensure the quality of the vaccines and diagnostics available to the marketplace. Testing product is a performance-based application that is science based and data driven. Through utilization of these systems, CVB prevents the marketing of serials of product that do not meet the standards set forth during licensure for purity, potency, safety, and efficacy.

Currently underway at the CVB are pilot projects concerning the methods used to select products for testing. CVB is exploring ways to identify and target problem products and firms and make the best use of limited resources. Accreditation of CVB-L to ISO 17025 standards will enhance consumer and stakeholder confidence in CVB test results and testing aids for the regulated industry.

The CVB is also increasing the review of test summary documents prepared by the regulated industry. Tentative future plans include administrative inspections that will allow on-site inspection time to focus more on the observations and audits of biological products.

3.12 Diagnostics

Two of the the key roles of VS are to repond to new, emerging disease threats and to control /manage/eradicate existing diseases. Performing accurate and timely diagnostic testing is an essential part of these VS roles. NVSL has identified the following testing programs as part of our GPRA mandate: tuberculosis, avian influenza, vesicular stomatitis, TSE's and brucellosis.

All of these testing programs have undergone an initial review by a outside panelists. Our goal, as part of the VS strategic plan, is to do repeat reviews over the next 5 years. The repeat reviews

will determine what, if any, improvements have been made in the original 5 testing programs and will help target areas that may still need work. The overall effect of these reviews is to improve NVSL's capability to provide improved laboratory support to disease investigation efforts and control/eradication programs. In addtion, these reviews are an important part of attaining and maintaining ISO 17025 laboratory accreditation, an important goal of NVSL in order to enhance its international and national status as a world-class reference laboratory.

Goal 4 - Expand the domestic and international marketability of U.S. animals, animal products, and biologics

4.1 Export Programs

VS anticipates continuing ongoing alliances such as the relationships of VS with such organizations as the American Horse Council, Livestock Exporters Association, and Certified Semen Services for purposes of assuring that markets are identified, and that export protocols are developed in such a manner that VS can continue to offer credible health certifications to our new trading partners. VS is open to partnering with other groups to the same end, to retain existing markets and open any new ones.

Regarding efforts in Aquaculture, VS will meet or exceed the anticipated 53 export markets targeted for FY 2003. The Aquatic Animal Health Program has developed voluntary inspection and certification programs in 10 states, and continues to grow. VS is working to remove unfair trade restrictions imposed by some trade partners, notably taking aggressive actions against Chile, and are advancing into markets in Japan, China and the United Kingdom. VS is also accessing an entirely new shellfish markets in Brazil. Currently, aquaculture represents a six billion dollar trade deficit, but has tremendous growth potential and a high degree of interest.

Electronic certifications for poultry into Canada are in use in 9 additional States, and the National Center for Import and Export has been in contact with the Veterinary Services of Mexico (SAGAR) regarding this issue. Mexico is receptive to electronic certification and will support our efforts in this direction. VS anticipates that 100 percent of all health certificates for animals will be issued electronically by FY 2004.

4.2 Veterinary Accreditation

VS has a long history of cooperation with the veterinary community in performing important regulatory work nationwide. While a simple accreditation process of life-time certification with no re-certification of credentials has served the United States well in the past, the National Veterinary Accreditation Program needs to be enhanced and modernized to ensure that accredited veterinarians have the tools needed to further advance disease prevention and emergency preparedness in the U.S.

The United States is unique in that it is the largest industrialized country to extensively use private veterinary practitioners to perform regulatory work. With increasing emphasis on international trade and disease regionalization, the U.S is now coming under a great deal of international

scrutiny for this use of private veterinarians to perform official government functions. Without a change in the accreditation process, the U.S. risks losing credibility with our international trading partners and stakeholders resulting in serious trade consequences for clients of veterinary practitioners, horse owners and food animal producers.

Increased global trade, travel, and foreign and emerging diseases and organisms put our country at risk for the introduction of a threat to animal, and even human, health. This necessitates that veterinarians keep abreast of these developments throughout their professional careers.

VS recognizes the need to modernize the accreditation process to reflect the complexities of the veterinary environment. VS has worked to develop new program initiatives designed to increase the effectiveness, credibility, and quality of the accreditation program. These new initiatives will strengthen the partnership between private and Federal veterinary sectors. Ultimately, the goal of the program is for the APHIS, private practitioners, and State animal health officials to work cooperatively to protect and improve the health, quality, and marketability of the U.S. animal population through detecting, preventing, controlling, and eradicating diseases that can negatively impact producers and public health in the United States.

4.3 Disease Status Certification

✓ aquaculture

The Animal and Plant Health Inspection Service (APHIS) has provided assistance upon request to aquaculture producers over the last thirty years. APHIS' role in aquaculture is to assist the aquaculture industry in controlling pests and diseases of economic importance, to facilitate the movement of aquatic animals and products in interstate and international commerce, and to improve the health and production of aquatic species.

USDA, APHIS,Veterinary Services (VS) is the recognized competent authority at the Federal level under OIE with legislative mandate to issue animal health inspections and certifications of aquatic animals and their animal products for international exportation.

The VS National Aquaculture Program mission is to work with aquaculture industries and other stakeholders to protect the health of aquatic animals, identify and respond to aquatic animal health emergencies, and to facilitate both interstate and international movement of aquatic animals and animal products. A major component of the APHIS National Aquaculture Program is the National Aquatic Animal Health Certification and Inspection Program (NAAHCIP). Aquaculture diseases are also being reported to the National Animal Health Reporting System (NAHRS) a system coordinated by APHIS to provide information on our nation's animal health status.

NAAHCIP is composed of an aquatic animal health certification and farm inspection component and an established procedure for approving laboratories for international export. Aquatic animal health certificates are endorsed by the APHIS Area Veterinarian-In-Charge for that State provided that samples are taken by a USDA-accredited veterinarian and the testing is conducted by an APHIS-approved laboratory.

Under the National Aquaculture Program, APHIS can certify under certain conditions disease freedom of all viral OIE Notifiable Diseases of Fish, including epizootic hematopoietic necrosis (EHN), oncorhynchus Masou virus disease (OMV), viral hemorrhagic septicemia (VHS), spring viremia of carp (SVC) and infectious hematopoietic necrosis (IHN). APHIS can also certify under certain conditions OIE "Other Significant Diseases" e.g., infectious salmon anemia (ISA) and infectious pancreatic necrosis (IPN). Other diseases can be tested and appropriate safeguarding assurances can be made.

APHIS is seeking to expand the current aquaculture program through rulemaking into a National Aquatic Animal Health Program that would provide the same services for aquaculture as are currently provided for traditional animal agriculture.

The goals of the National Aquatic Animal Health Program are: Goal 1: Facilitate international movement of aquatic animals and animal products; Goal 2: Create an effective aquatic disease surveillance and monitoring system; Goal 3: Create an aquatic disease emergency management system; and Goal 4: Facilitate interstate movement of aquatic animals and animal products.

✓ **sheep**

Flocks are certified free of scrapie based on the flock being in continuous compliance with the certification program standards for 5 years. This measure will be calculated using the flock status information entered into the GDB by each Area Office. VS will strive to enroll as many seed stock flocks in the certification program as possible in order to 1) make clean replacement stock available for producers and thereby prevent the reintroduction of scrapie into flocks, 2) quickly identify scrapie-infected seed stock flocks so that they can be cleaned up, and 3) enhance our ability to trade sheep, goats, and their products internationally.

4.4 Production Process Auditing and Certification

✓ **trichinae**

Of all food safety issues, perhaps few are better known to U.S. consumers than the one of trichinae in pork. Generations have been taught to overcook pork to ensure that the risk of trichinellosis is completely removed. Due to changes in modern-day pork production, trichinae infected pigs are a rarity and the trichinellosis threat to consumers is extremely low. Paradoxically, consumer concern over trichinellosis remains high. Furthermore, the U.S. is one of the few developed countries that does not directly address trichinae in its food safety system, relying instead on consumer education to excessively cook pork to control the parasite. U.S. producers encounter trade-related barriers in some countries due to the absense of trichinae control measures. To address consumer concerns, remove trichinae-related trade barriers, and to provide a framework for future, farm-based, food safety certification programs, APHIS is working with industry and allied agencies to develop the National Trichinae Herd Certification Program. The NTHCP ties together the activities of producers and packers, as well as three USDA agencies (APHIS, FSIS, and AMS), to ensure the trichinae-free status of pork-derived

food products. A myriad of technical and logistical details must be resolved before the program can become available nationally to all produces and packers. Toward this end, APHIS will: 1) finalize trichinae pilot efforts to provide the first, farm-through-slaughter, on-farm certification program in the history of U.S. production agriculture, and 2) collaborate with FSIS, AMS, and ARS to finalize implementation of the national trichinae herd certification program in major domestic slaughter facilities. By FY 2004, the certification program will be available to all packers and producers wishing to participate in this voluntary program.

✓ **auditing service delivery**

Increasingly, different segments of the food production chain, as well as domestic and international consumers, will look for additional assurances from their respective suppliers regarding specific food-product attributes. Packers will expect producers to provide (raw ingredients) raised under specific production conditions that, for example, assure such things as freedom from specific diseases or chemical residues, to overall product attributes such as "organic" or "animal welfare friendly". To protect food-chain buyers and suppliers, and ultimately consumers, that such process are indeed in place and being adherred to, these systems must periodically be audited to ensure compliance with established standards. Given its well developed field force, APHIS is in an excellent position to help provide U.S. producers and packers with an on-farm auditing service. The first step for APHIS in being able to provide this service, is to develop a field force knowledgable in various auditing techniques. Towards this end a training curricula, tailored to VS, will be established that teaches personnel both ISO-9000 and HACCP fundamentals. In partnership with AMS, VS will establish a USDA infrastructure to both market and provide standardization and auditing services to livestock production systems and export facilities. By FY 2004, auditing pilots will be running in 8 VS field offices.

✓ **toxoplasma**

Though modern production practices, coupled with implementation of the National Trichinae Herd Certification Program, will effectively eliminate trichinae as a food safety concern, the role of undercooked pork as a source of human toxoplasmsis is concurrently rising. Toxoplasma infection is of concern primarily in immune-compromised individuals such as the elderly, patients undergoing chemotherapy, and those infected with HIV. For this reason, producers, APHIS and allied federal agencies are initiating efforts to develop a process for certifying herds as having "toxoplasma safe" production practices. Because toxoplasma shares many of the same infection risk factors as trichinae, an additional certification program can readily be developed to address this parasite of public health concern. Before a toxoplasma certification program development can proceed, additional research must first be completed regarding infection risk factors and rapid screening test development. It is anticipated that needed research will be completed in 2002, allowing certification program development to proceed. During FY 2003 through FY 2005, certification pilots will be implemented in 2 major slaughter plants, involving producers from 3 key states.

- ✓ **egg quality assurance**

The President's Council on Food Safety has set a goal of reducing by 50 percent the incidence of human cases of *Salmonella* Enteritidis (SE) by the year 2005. Part of the plan to accomplish this goal is for FDA to develop a mandatory on farm quality assurance program to reduce the risk of SE infections in table egg layer flocks. Several states and industry groups already have such programs in place on a voluntary basis. VS has made itself available to audit one such program developed by the United Egg Producers (UEP). This VS-UEP cooperative program is currently on hold pending the development of the FDA program. VS has also signaled to FDA our availability to conduct on farm audits for their upcoming mandatory quality assurance program.

4.5 Diagnostics

In order to expand the domestic and international marketability of U.S. animals and animal products, it will be important to make the diagnostic testing associated with the marketing of animals and animal products more accessible to livestock producers. As NVSL and university/state laboratories work towards ISO 17025 accreditation, the laboratory approval process/proficiency testing will play a crucial role in meeting this standard. In order to facilitate this need, during FY2001 through FY 2004 NVSL will attempt to increase the number of approved laboratories by 5 percent thereby increasing the accessibility of testing for animal movement or certification/eradication along with increasing the quality of this testing.

4.6 Biologics

Today's market needs go beyond our domestic borders. The Center for Veterinary Biologics (CVB) is continuing its efforts to reduce trade barriers that limit the sale of veterinary biological products overseas. CVB officials continue discussions with representatives of the European and U.S. biologics industries and with regulatory officials from the European Union (EU) regarding a Mutual Recognition Agreement (MRA) for the marketing of veterinary biologics. Once obtained, ISO accreditation of CVB-L will increase recognition of CVB results and increase the use of CVB reagents internationally, enhancing movement of product worldwide.

CVB was involved in the creation of the Committee of the Americas for the Harmonization of Registration and Control of Veterinary Medicines (CAMEVET) and participated in the first meeting. This committee consists of representatives of the Official Services from the OIE member countries in the Americas responsible for regulating veterinary medicinal products. The objectives of CAMEVET include the coordination of the technical information for the registration and control of veterinary medicines with the intention of harmonizing the technical procedures to improve the quality of the veterinary medicines and the trade of the products among the countries and the exchange of information about regulatory requirements and techniques and scientific advances dealing with quality and control of veterinary medicines.

CVB actively participates in the Veterinary International Cooperation on Harmonization (VICH). During FY 2000, the 6th and 7th Steering Committee Meetings for VICH were held to review

the progress of five working groups addressing projects concerning the harmonization of quality test requirements and post licensing monitoring procedures (pharmacovigilance) for veterinary biological products. Two of the working groups finalized proposed harmonized guidelines for Stability and Good Clinical Practices and released them for implementation. The other two working groups have prepared draft guidelines on pharmacovigilance and quality monitoring. The drafts were released for industry comment in 2000. A fifth working group on target animal safety was initiated. The Steering Committee and working groups will remain active through FY 2005.

Harmonization of test standards will require the production, testing, and distribution of international references. The CVB will become a supplier of these international standards, financing this additional activity through a user fee basis.

CVB is also working with other international regulatory agencies to ensure the availability of vaccines for foreign animal diseases. CVB has participated in on-site facility inspections and conducted record reviews for these vaccines. An emergency plan is in place and CVB's role is well defined. The plan includes steps to be taken to obtain the needed vaccine in a timely fashion.